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Yuasa et al.

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(45) **Date of Patent: Feb. 4, 2025**

(54) **CLIP DEVICE FOR ENDOSCOPE**

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(73) Assignee: **Olympus Medical Systems Corp.**, Tokyo (JP)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 385 days.

(21) Appl. No.: **17/668,457**

(22) Filed: **Feb. 10, 2022**

(65) **Prior Publication Data**

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Related U.S. Application Data

(60) Provisional application No. 63/148,655, filed on Feb. 12, 2021.

(51) **Int. Cl.**
A61B 17/08 (2006.01)
A61B 17/00 (2006.01)

(52) **U.S. Cl.**
CPC ***A61B 17/083*** (2013.01); ***A61B 17/00234*** (2013.01); *A61B 2017/088* (2013.01)

(58) **Field of Classification Search**
CPC A61B 17/083; A61B 17/00234; A61B 2017/088
See application file for complete search history.

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Primary Examiner — Shaun L David
Assistant Examiner — Rachael L Geiger
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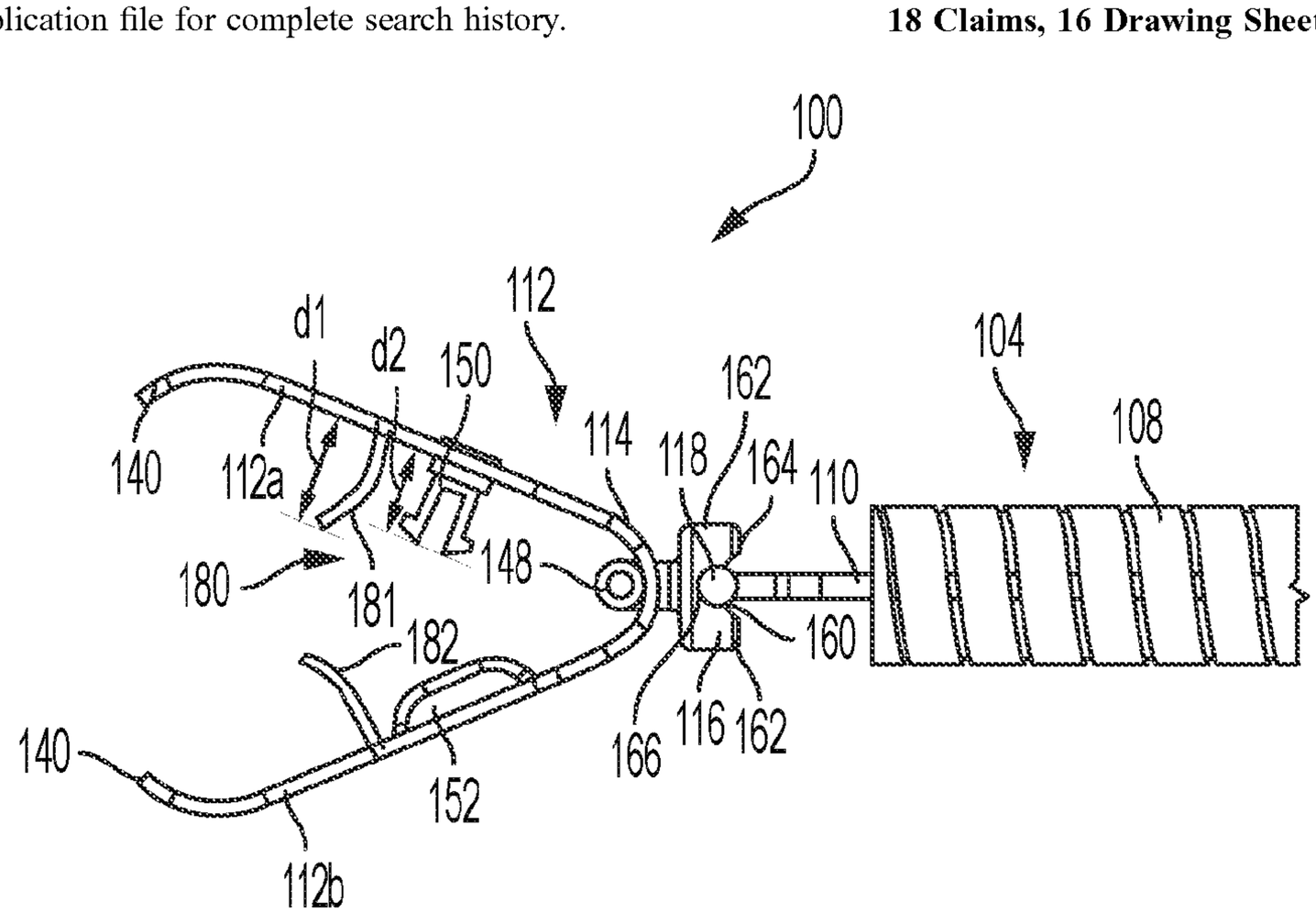
(57) **ABSTRACT**

A clip device includes a sheath having a lumen with at least one open end and a plurality of clip arms movable between a first configuration in which the plurality of clip arms are opened to receive a target tissue, and a second configuration in which the plurality of clip arms are closed to grip the target tissue. Locking mechanisms respectively provided on the plurality of clip arms engage one another for maintaining the second configuration. A restraining mechanism is optionally configured to be associated with the locking mechanisms to prevent the target tissue from being pinched between the locking mechanisms.

18 Claims, 16 Drawing Sheets



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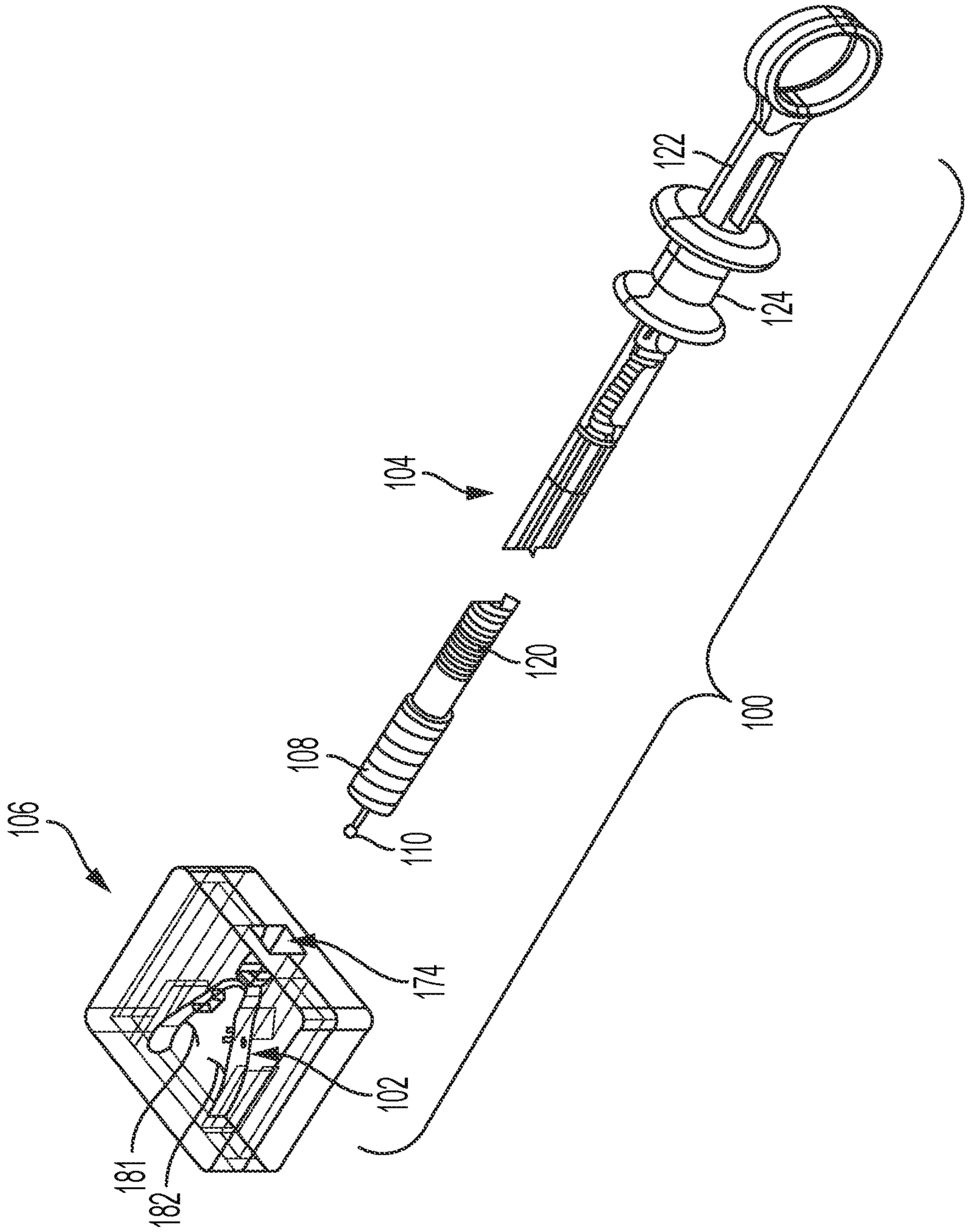

FIG. 1

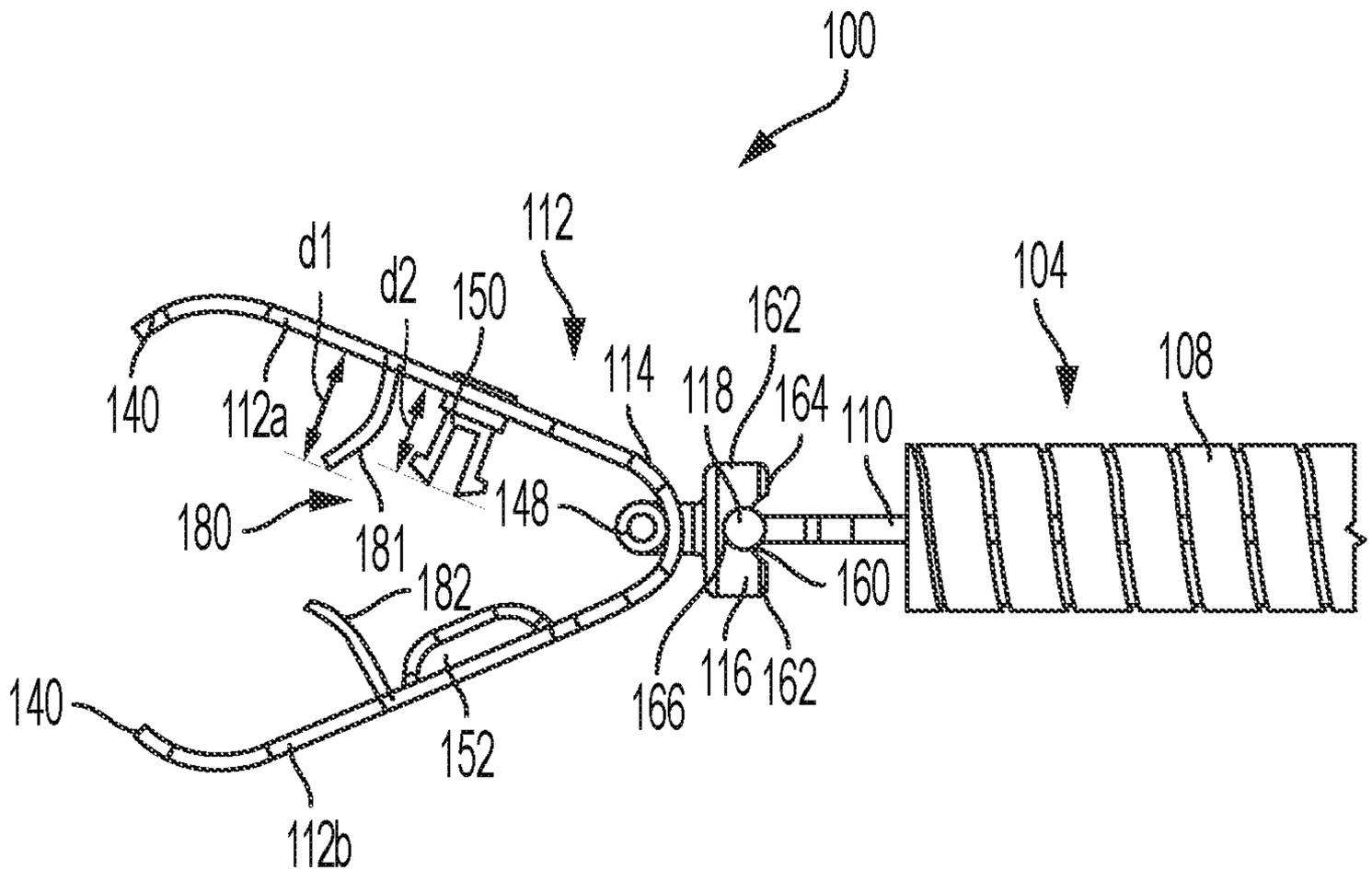
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FIG. 2

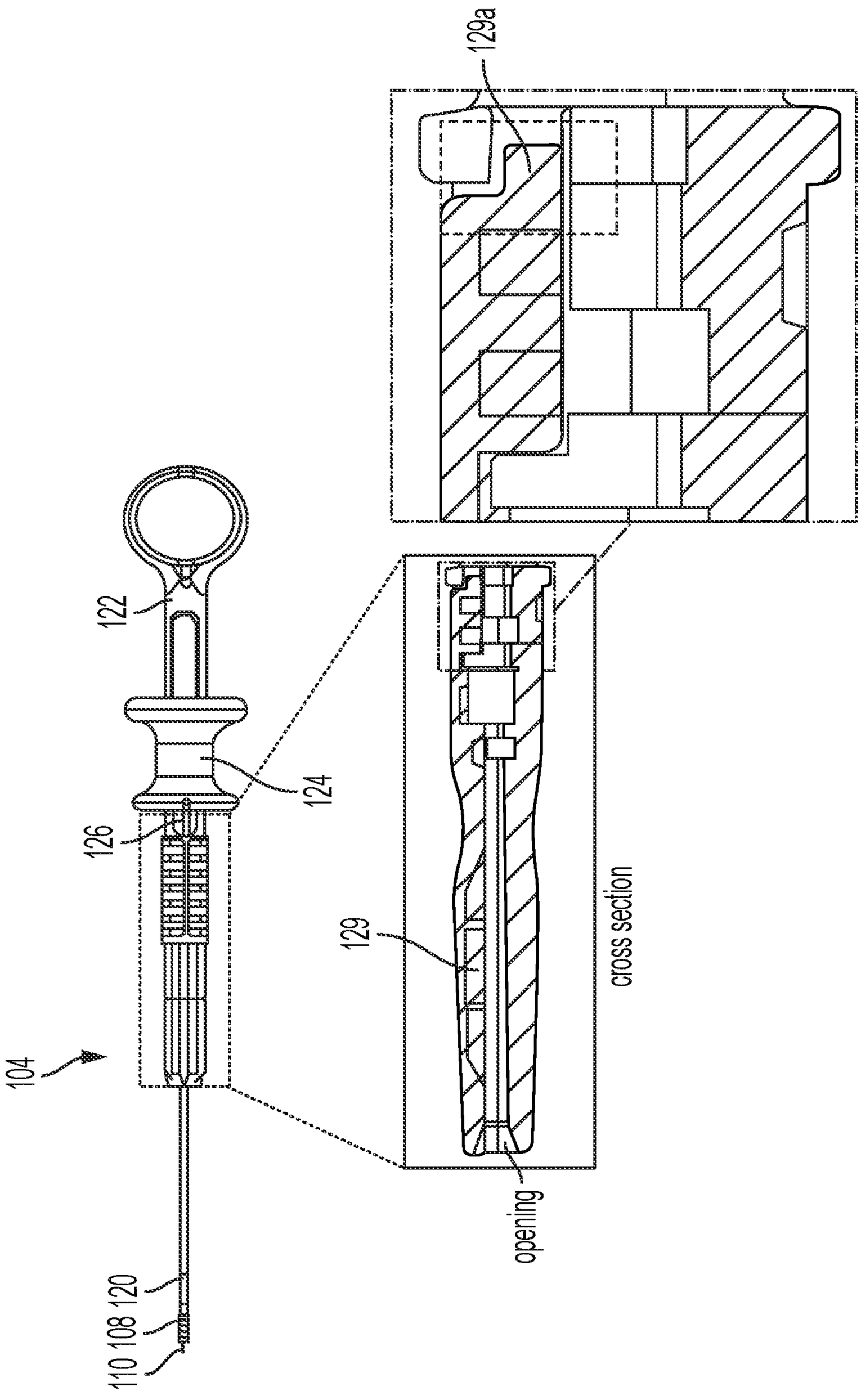


FIG. 3

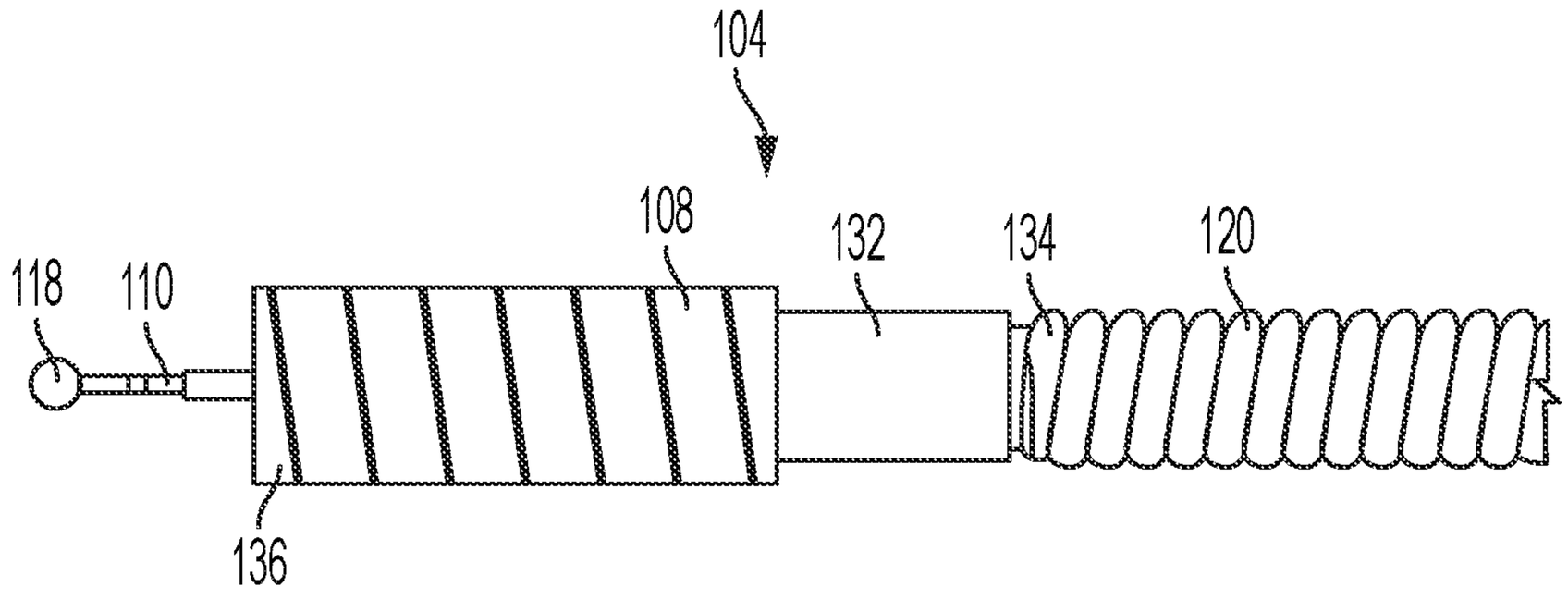


FIG. 4

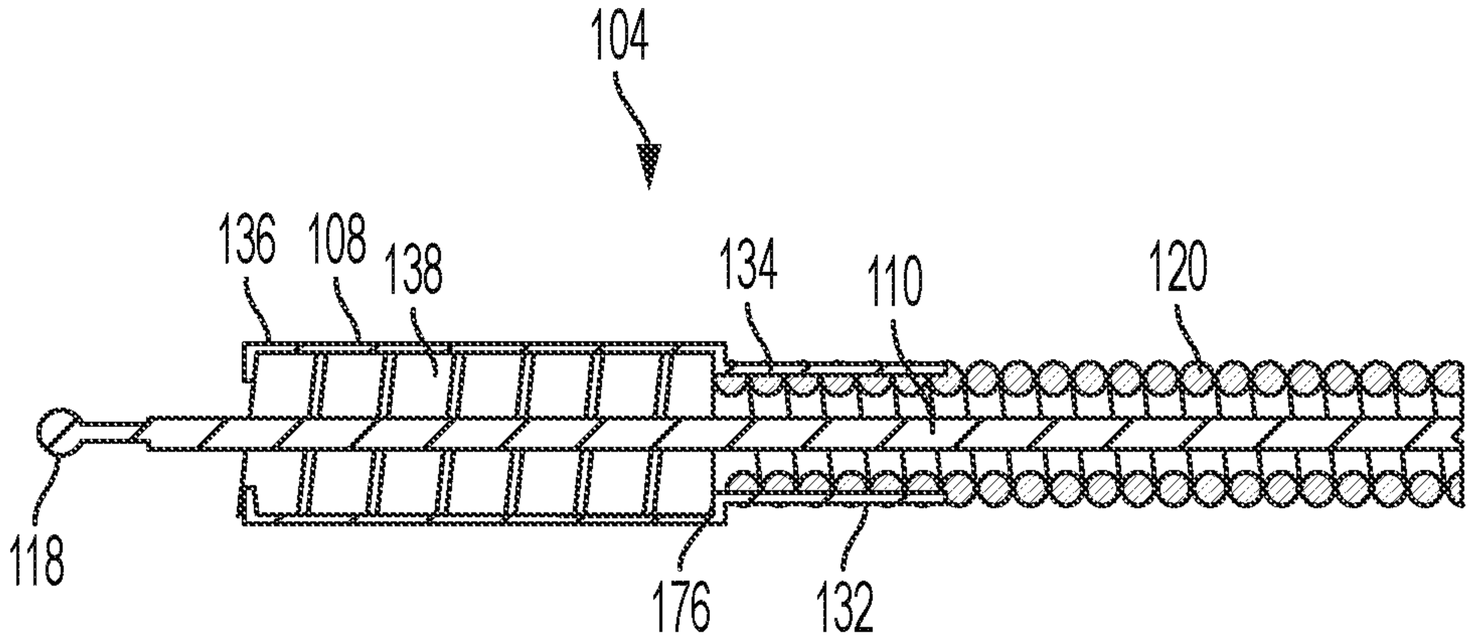


FIG. 5

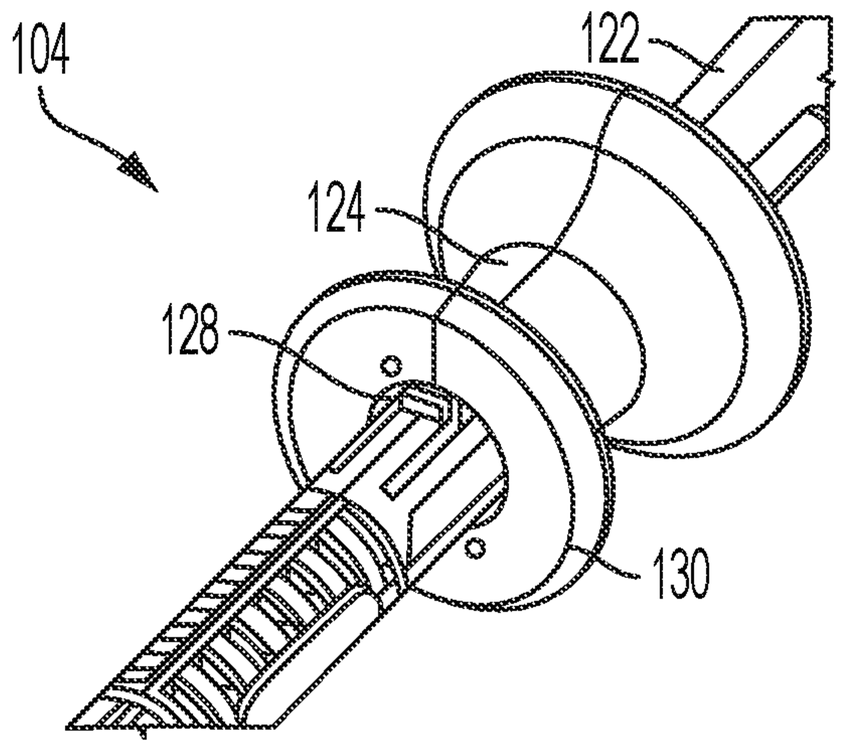


FIG.6

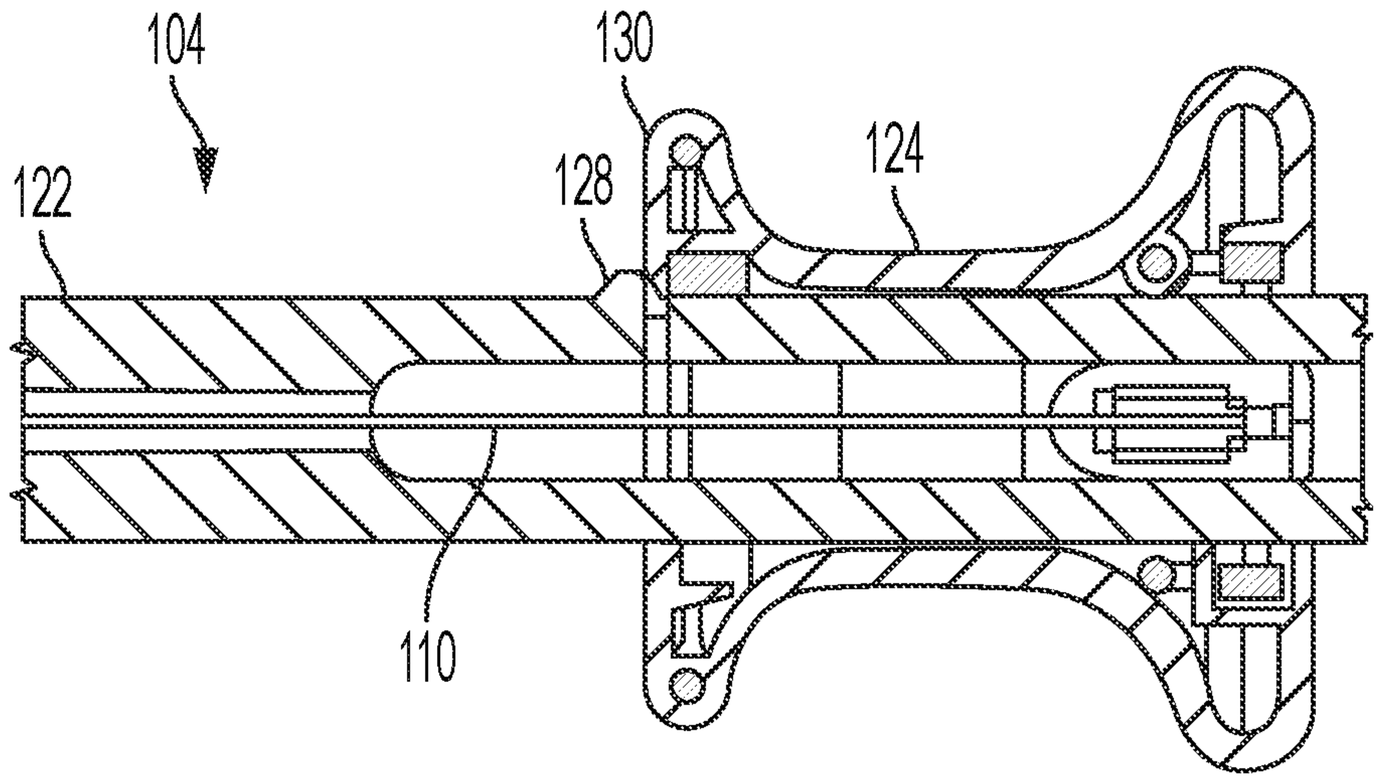


FIG. 7

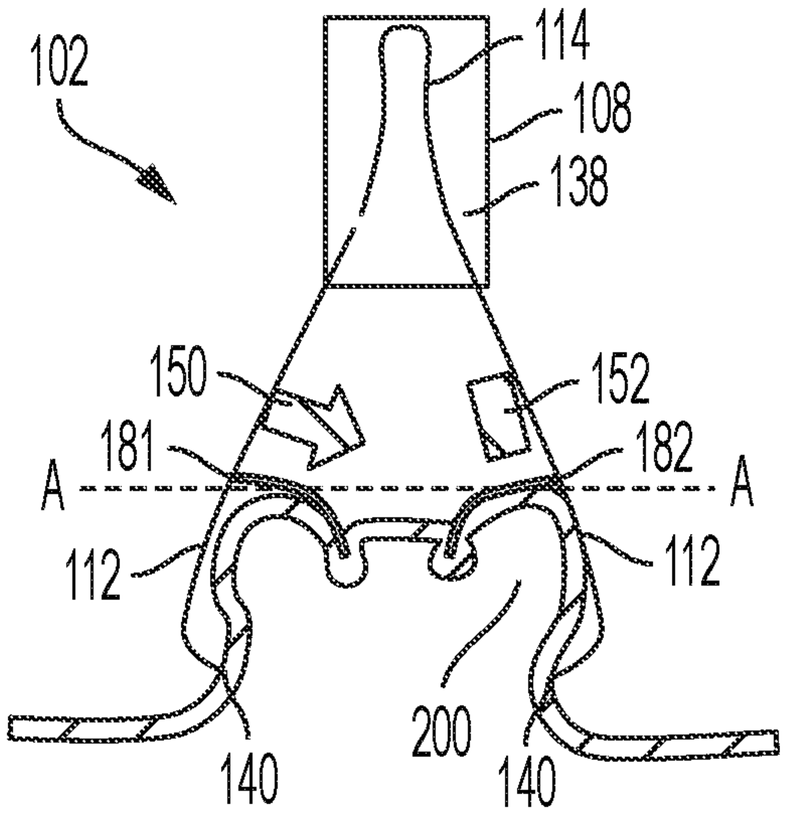


FIG. 8A

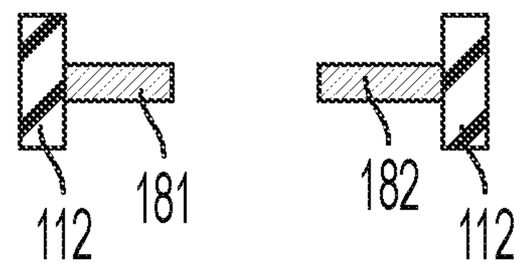


FIG. 8B

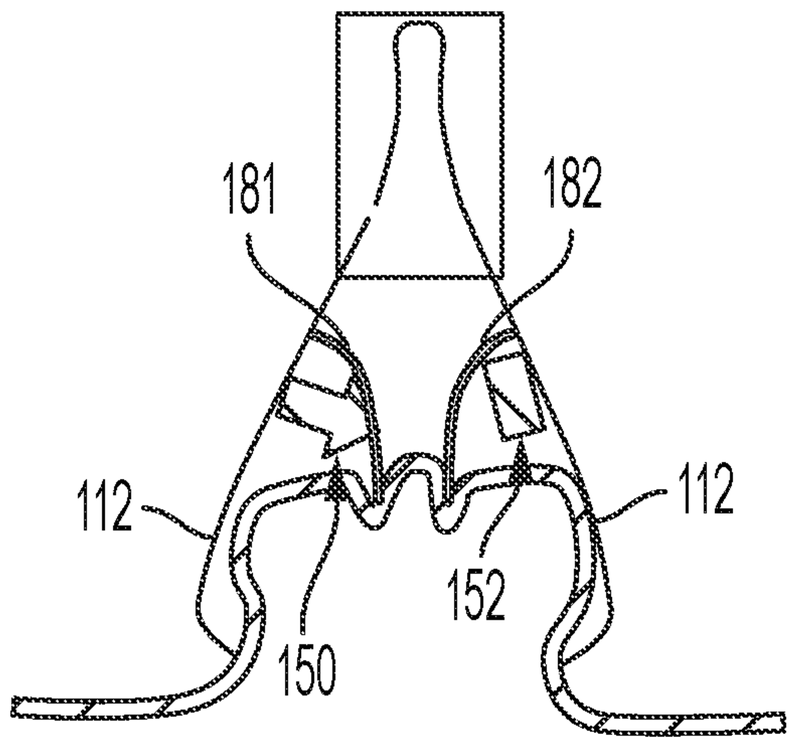


FIG. 8C

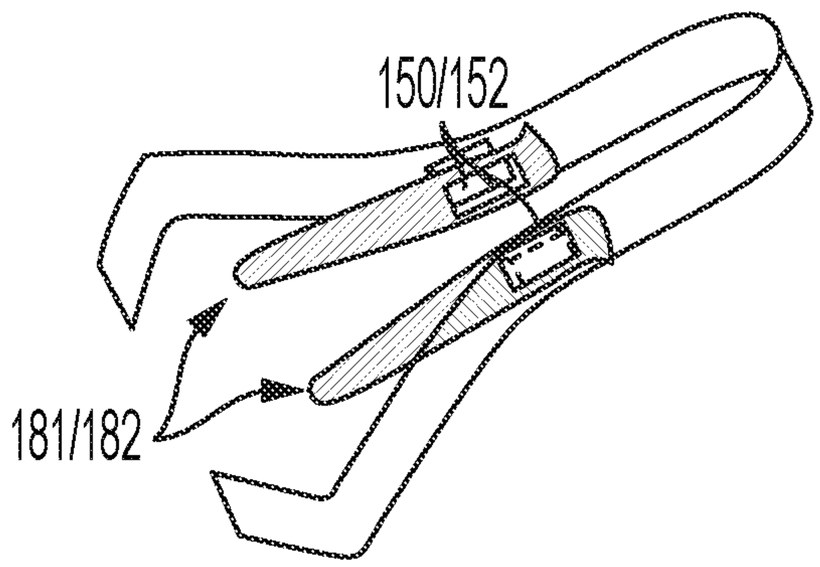
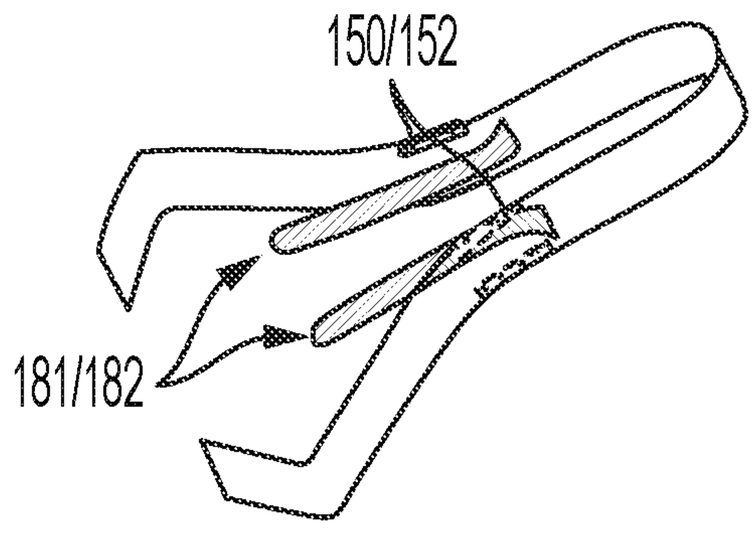


FIG. 8D



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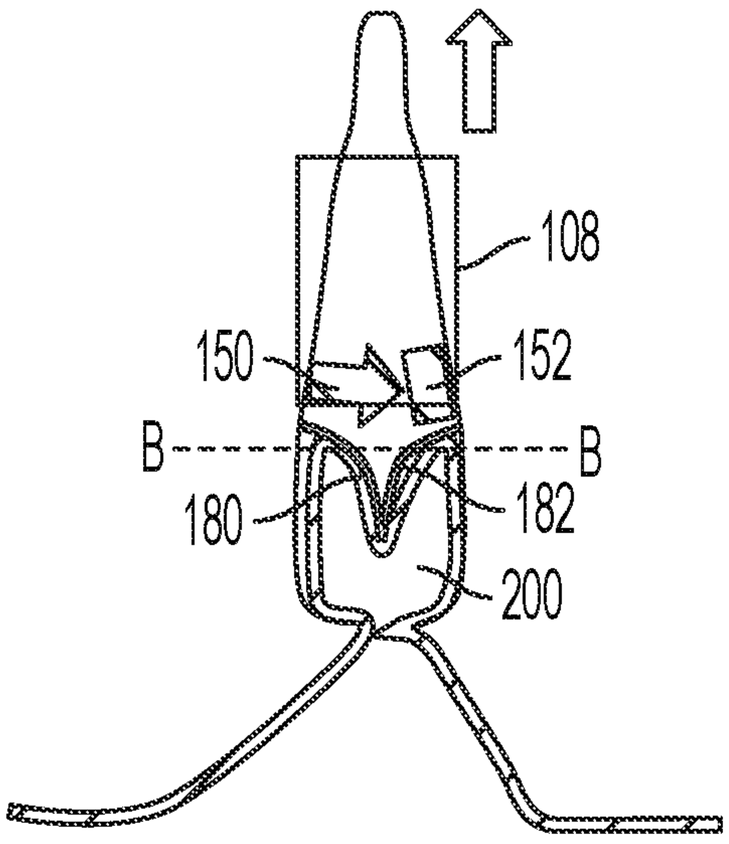


FIG. 9A

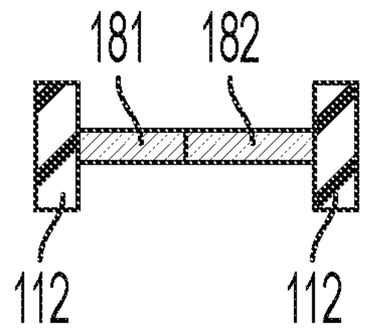


FIG. 9B

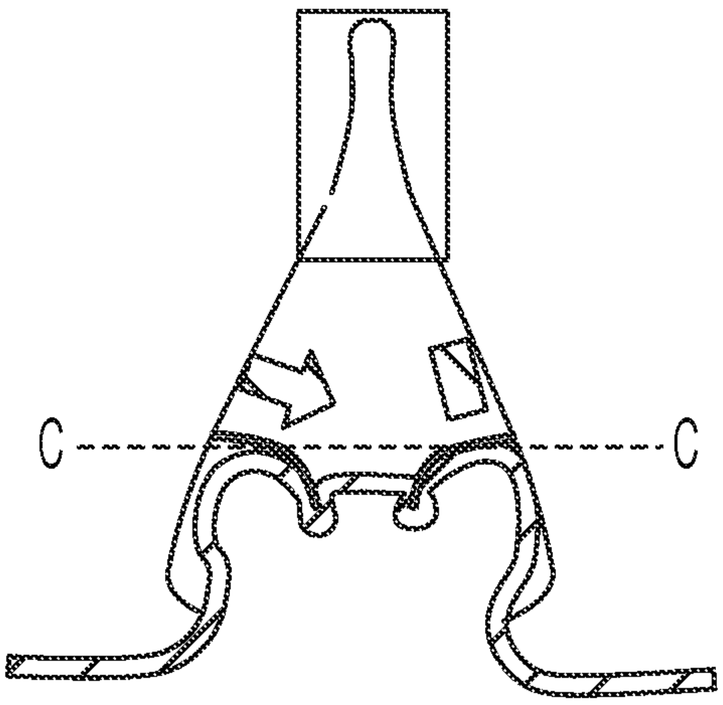


FIG. 10A

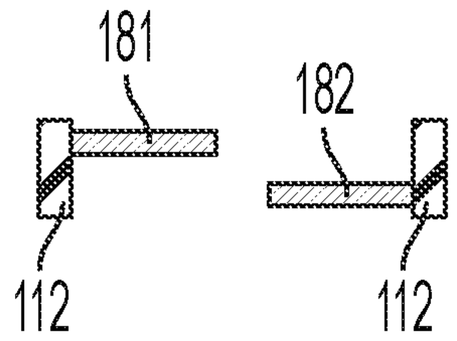


FIG. 10B

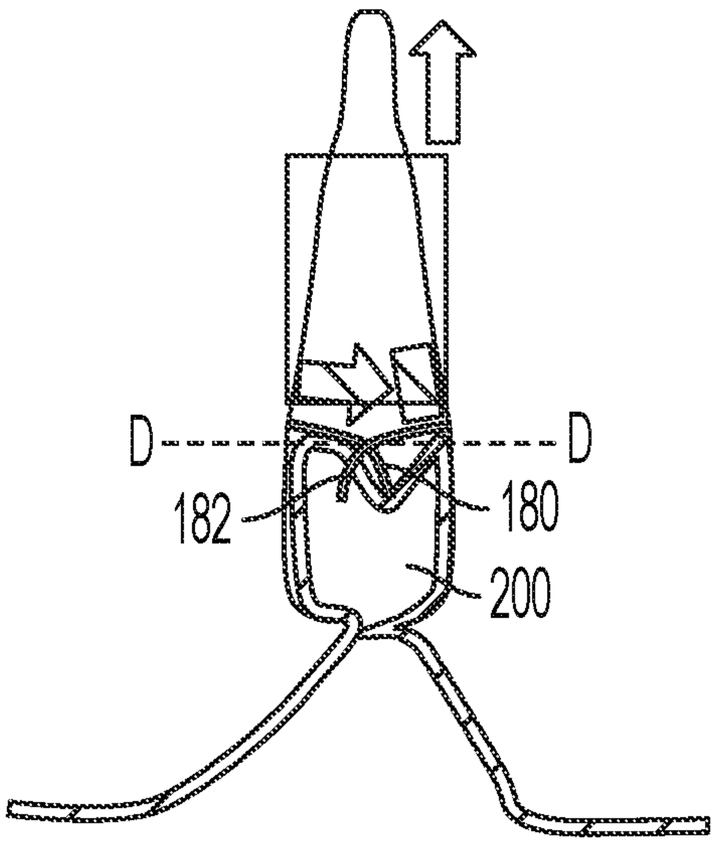


FIG. 11A

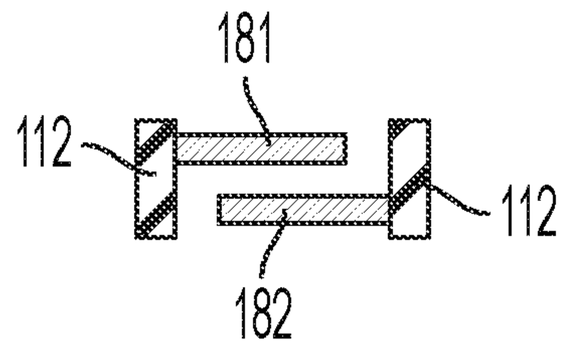


FIG. 11B

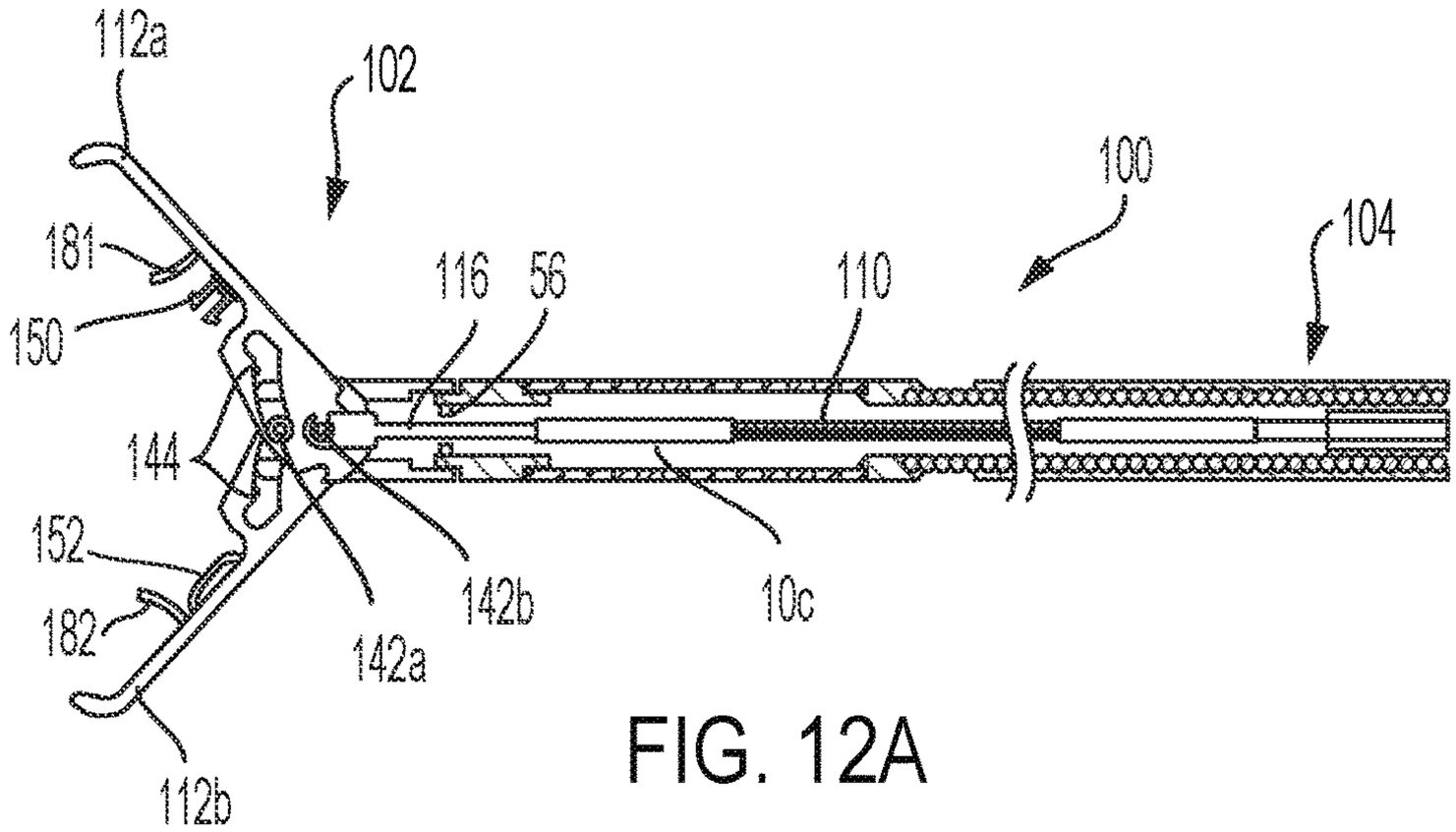


FIG. 12A

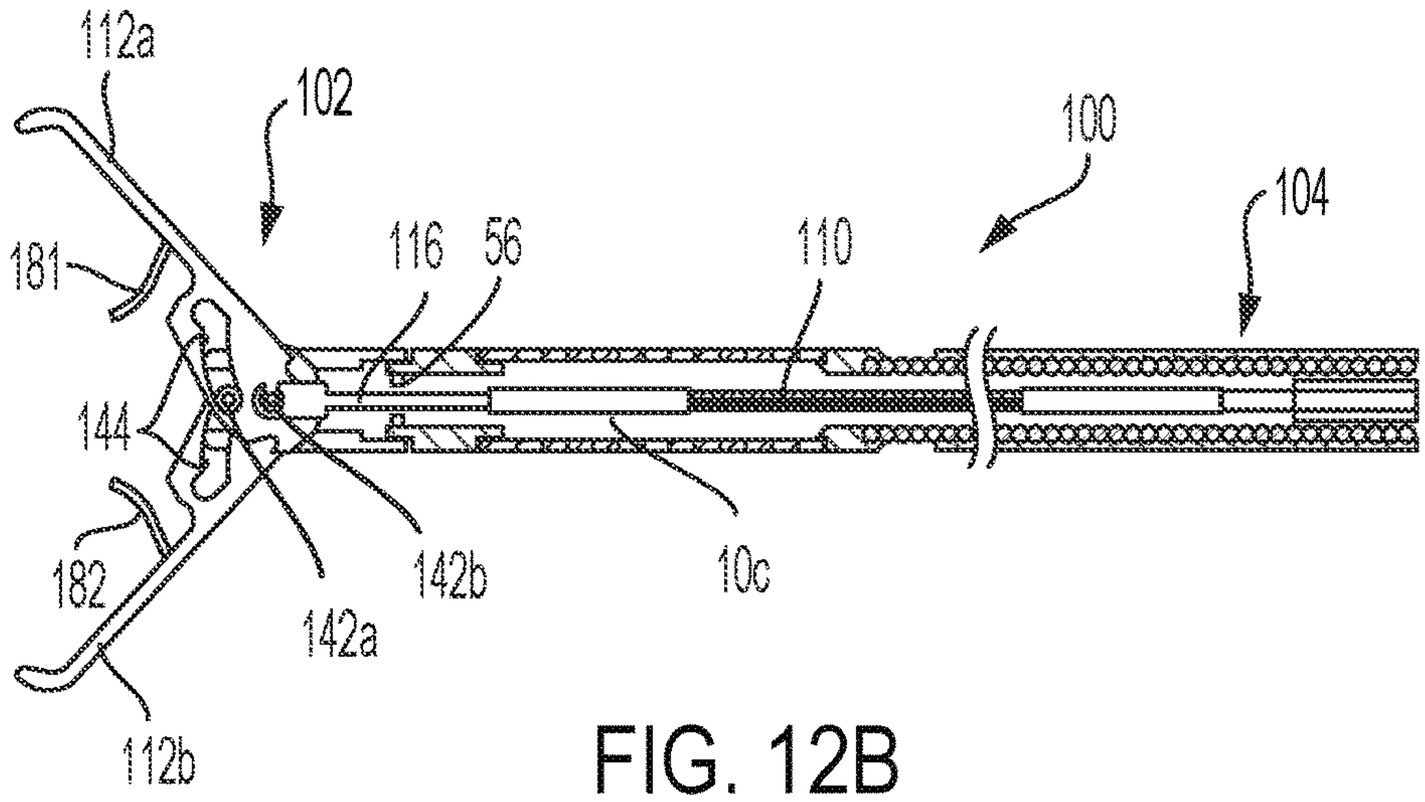


FIG. 12B

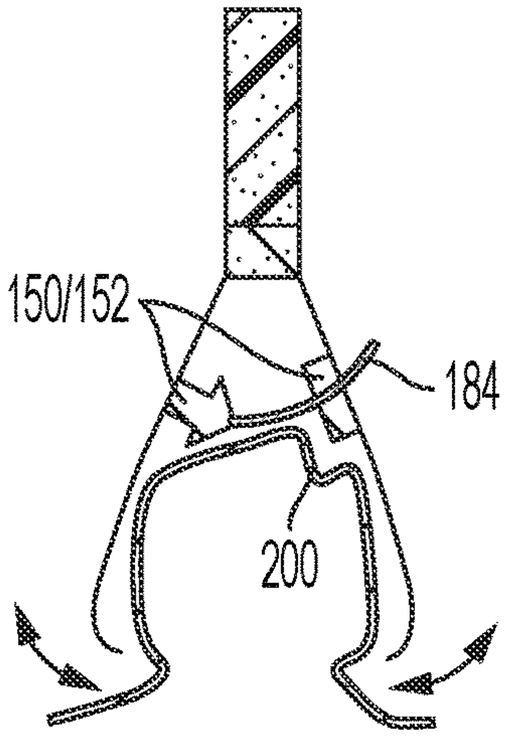
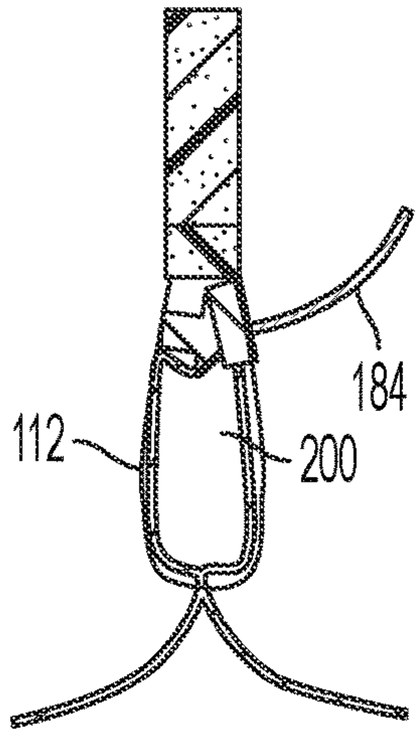


FIG. 13A



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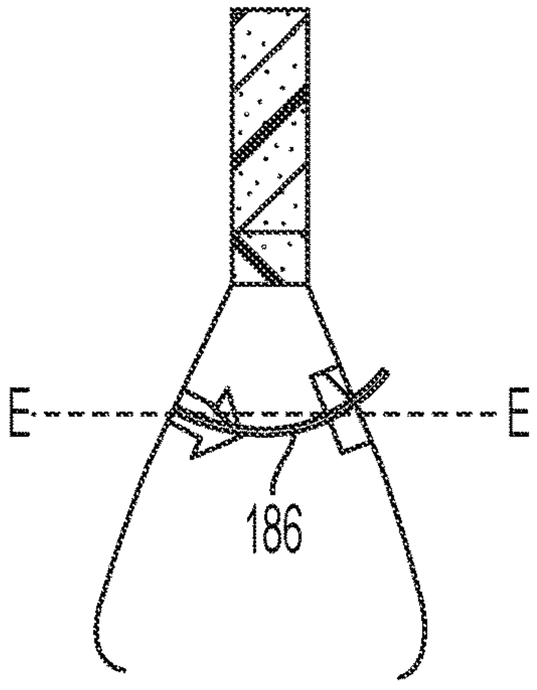

FIG. 14A

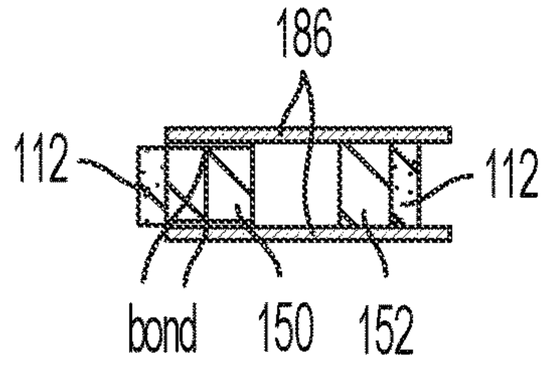

FIG. 14B

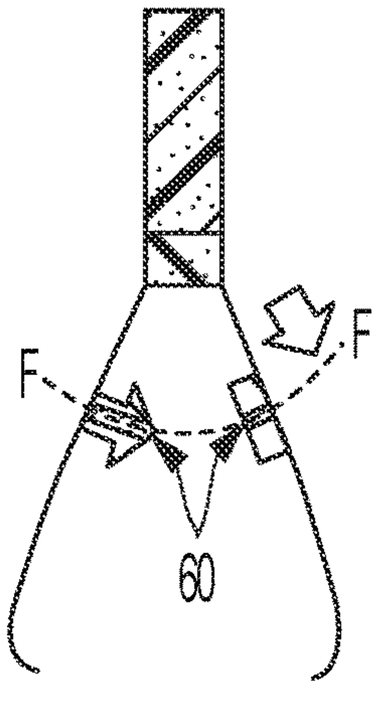

FIG. 15A

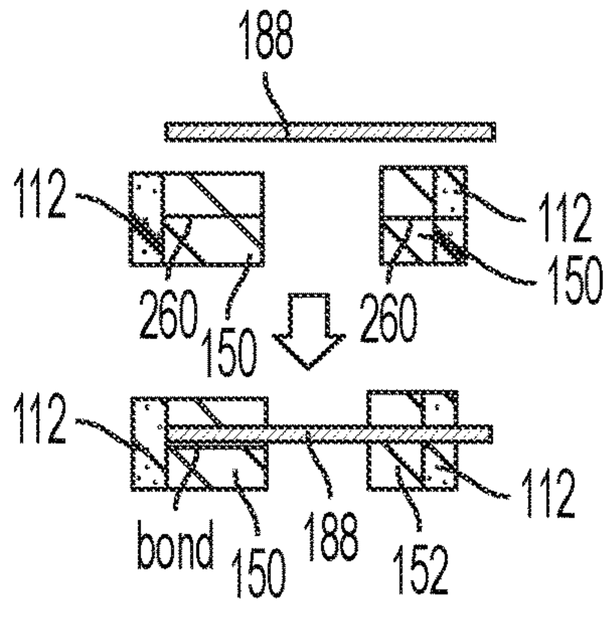

FIG. 15B

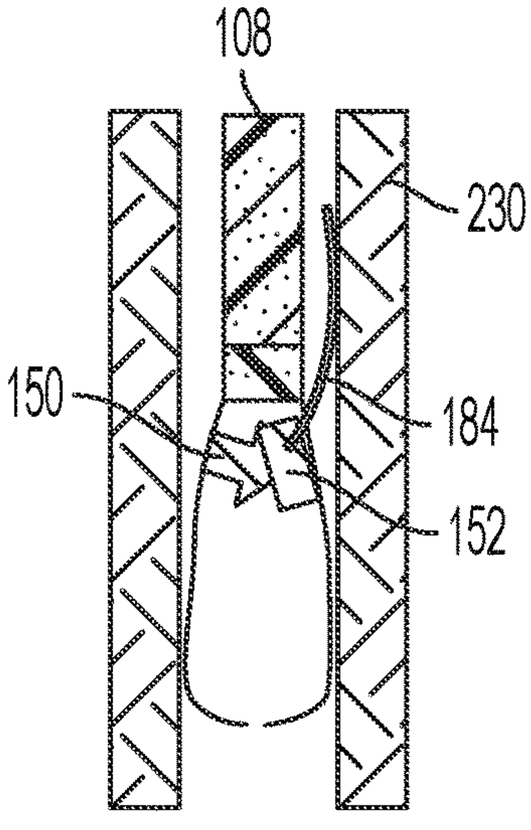

FIG. 16

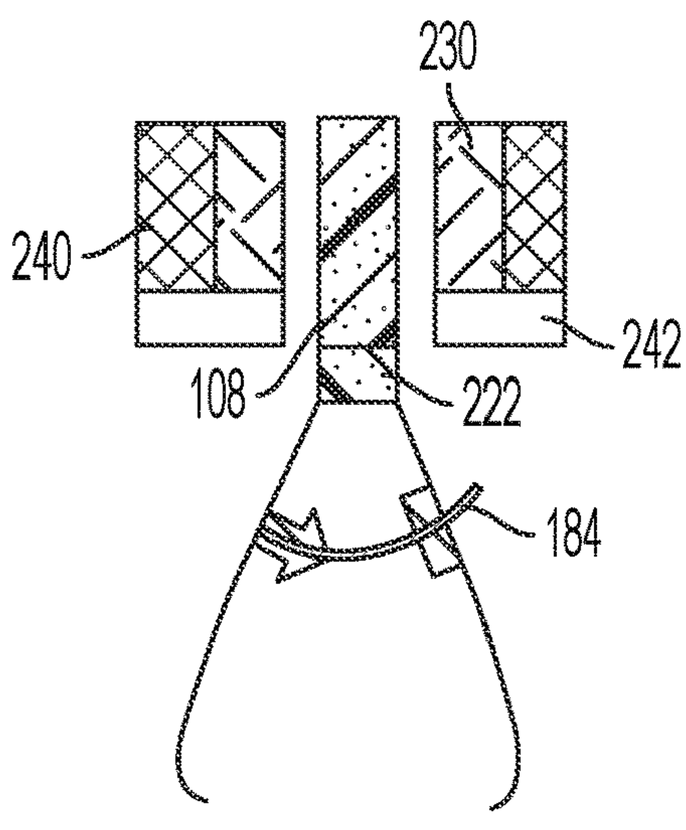

FIG. 17

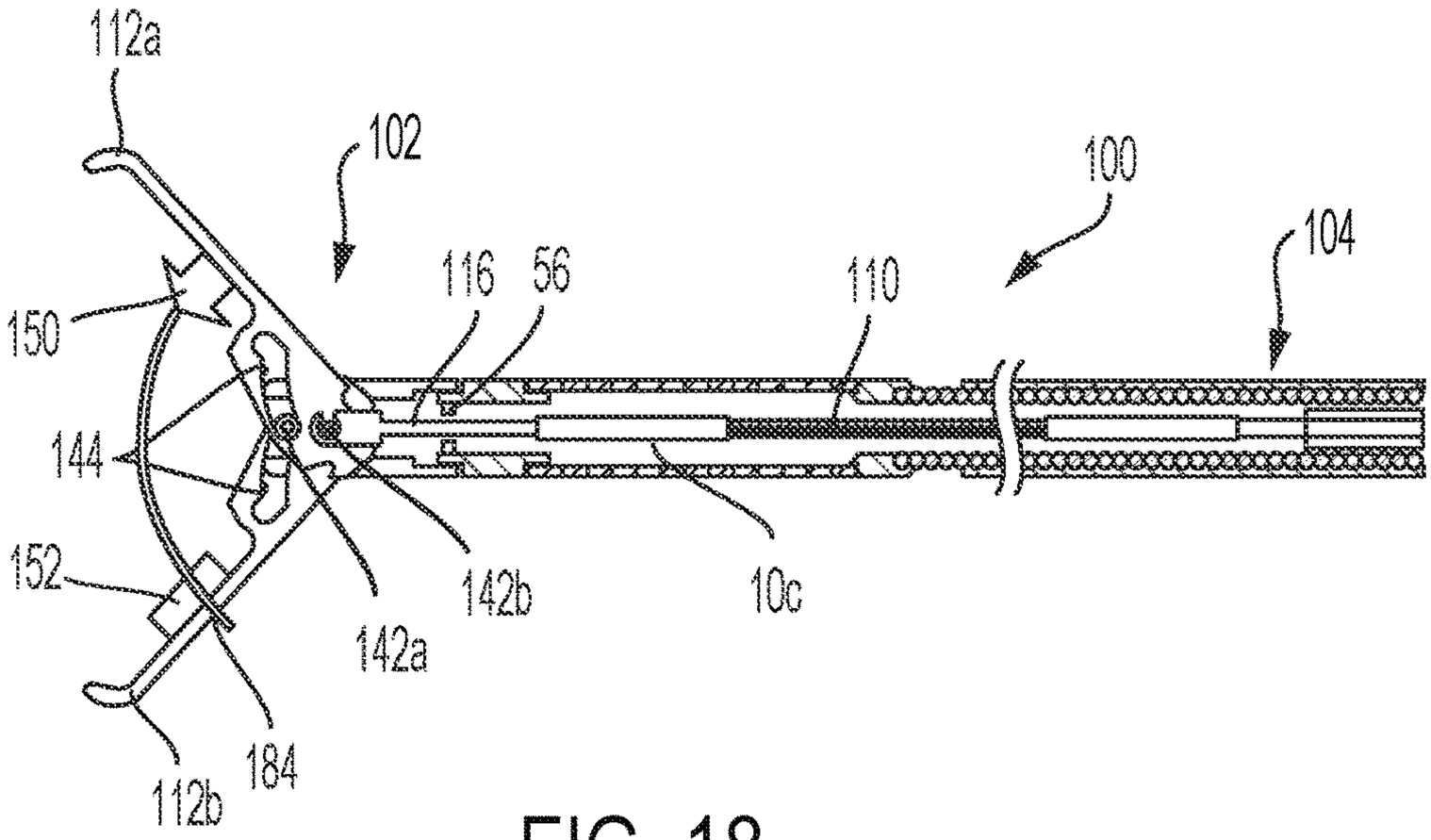

FIG. 18

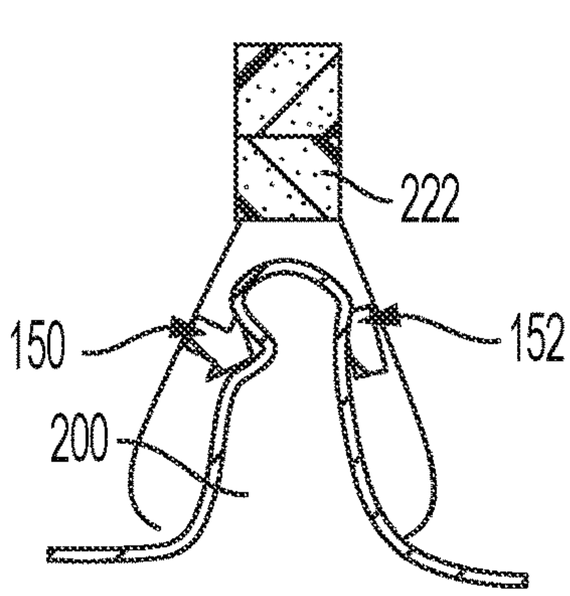

FIG. 19A

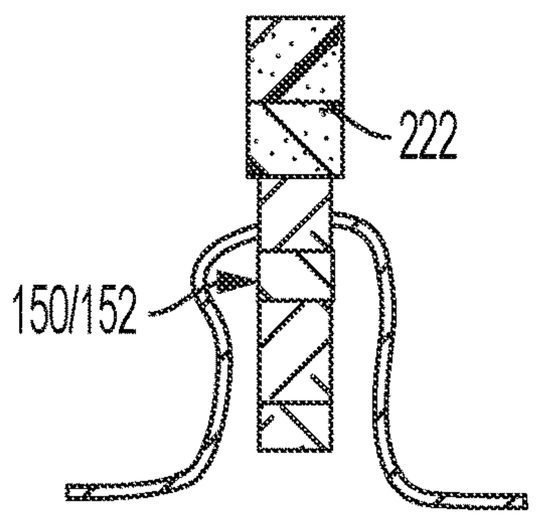

FIG. 19B

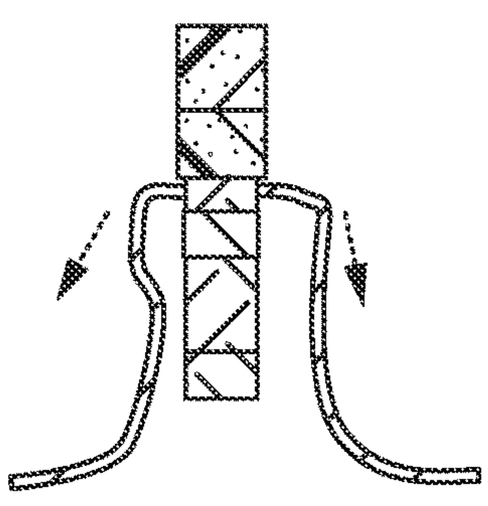

FIG. 19C

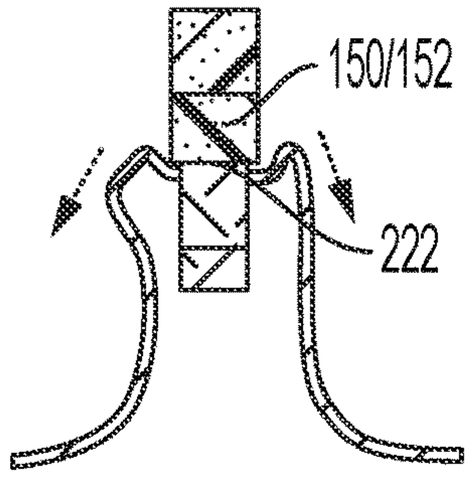

FIG. 19D

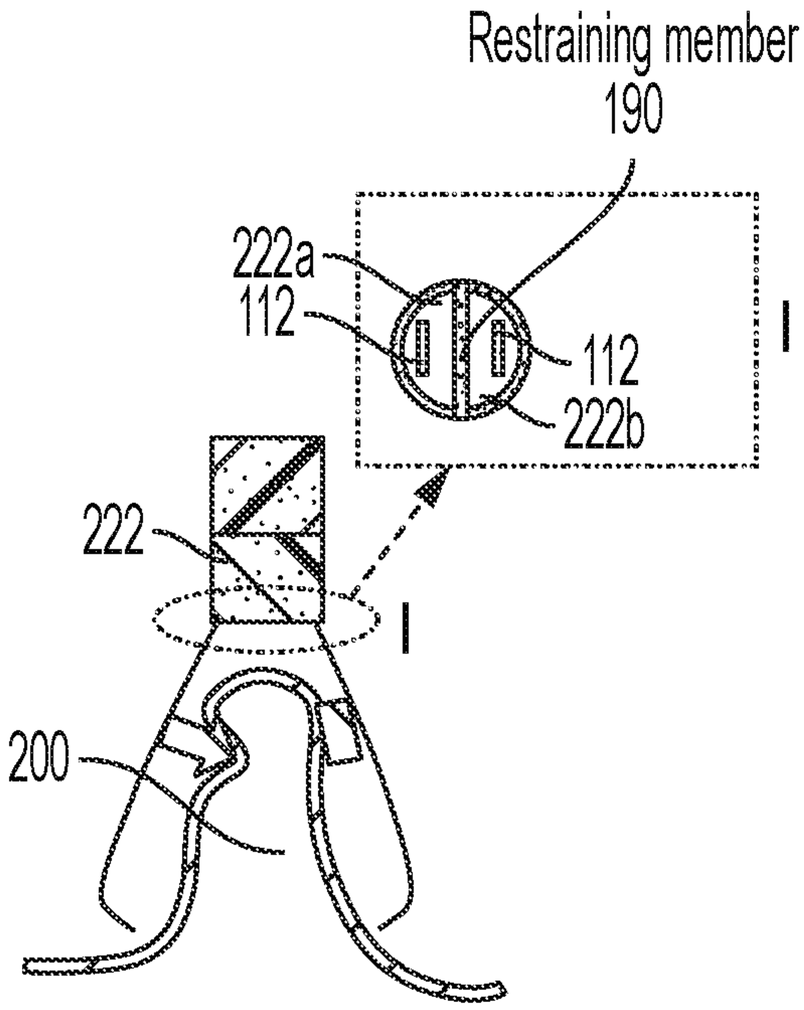

FIG. 20A

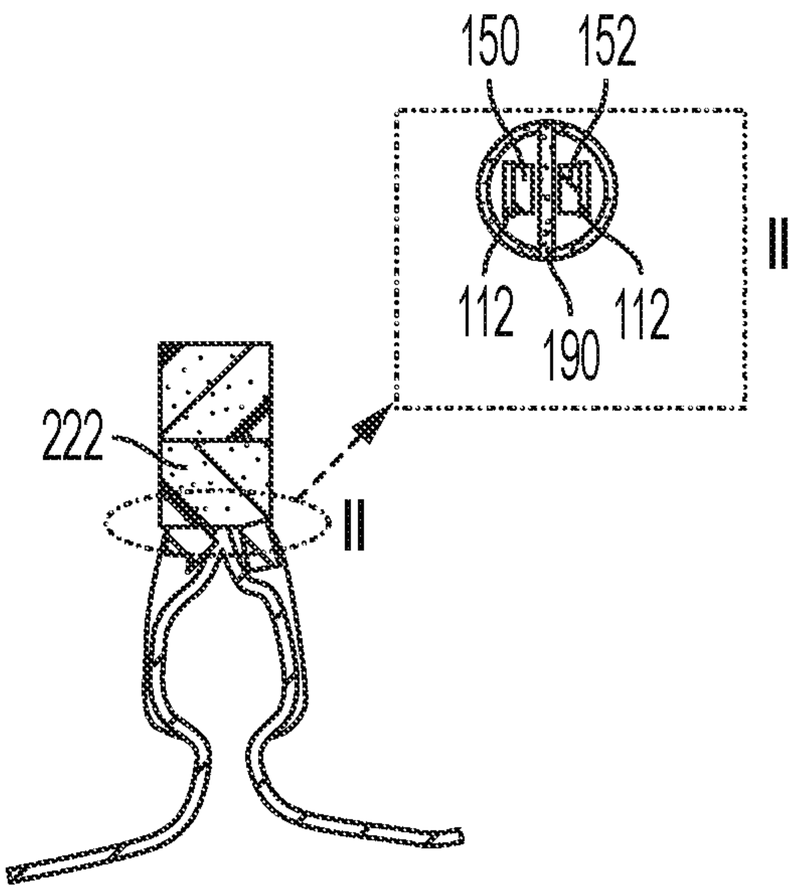

FIG. 20B

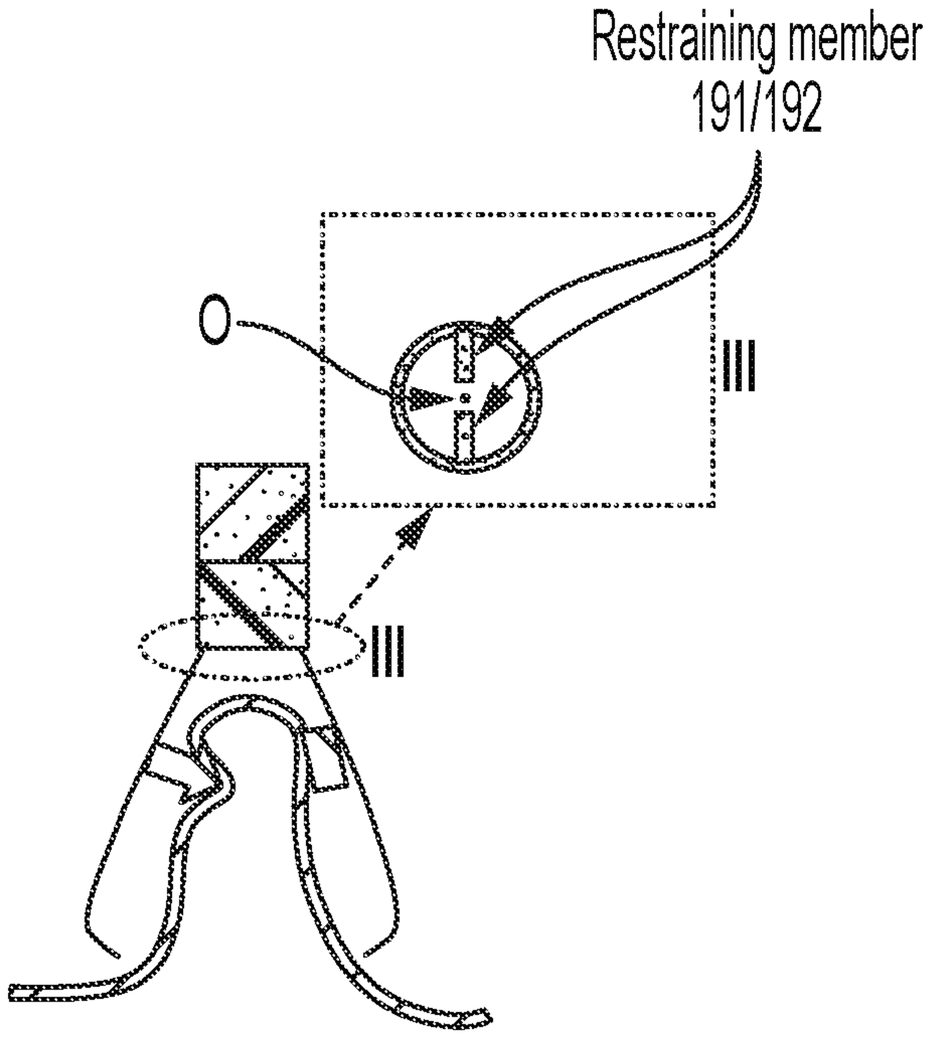

FIG. 20C

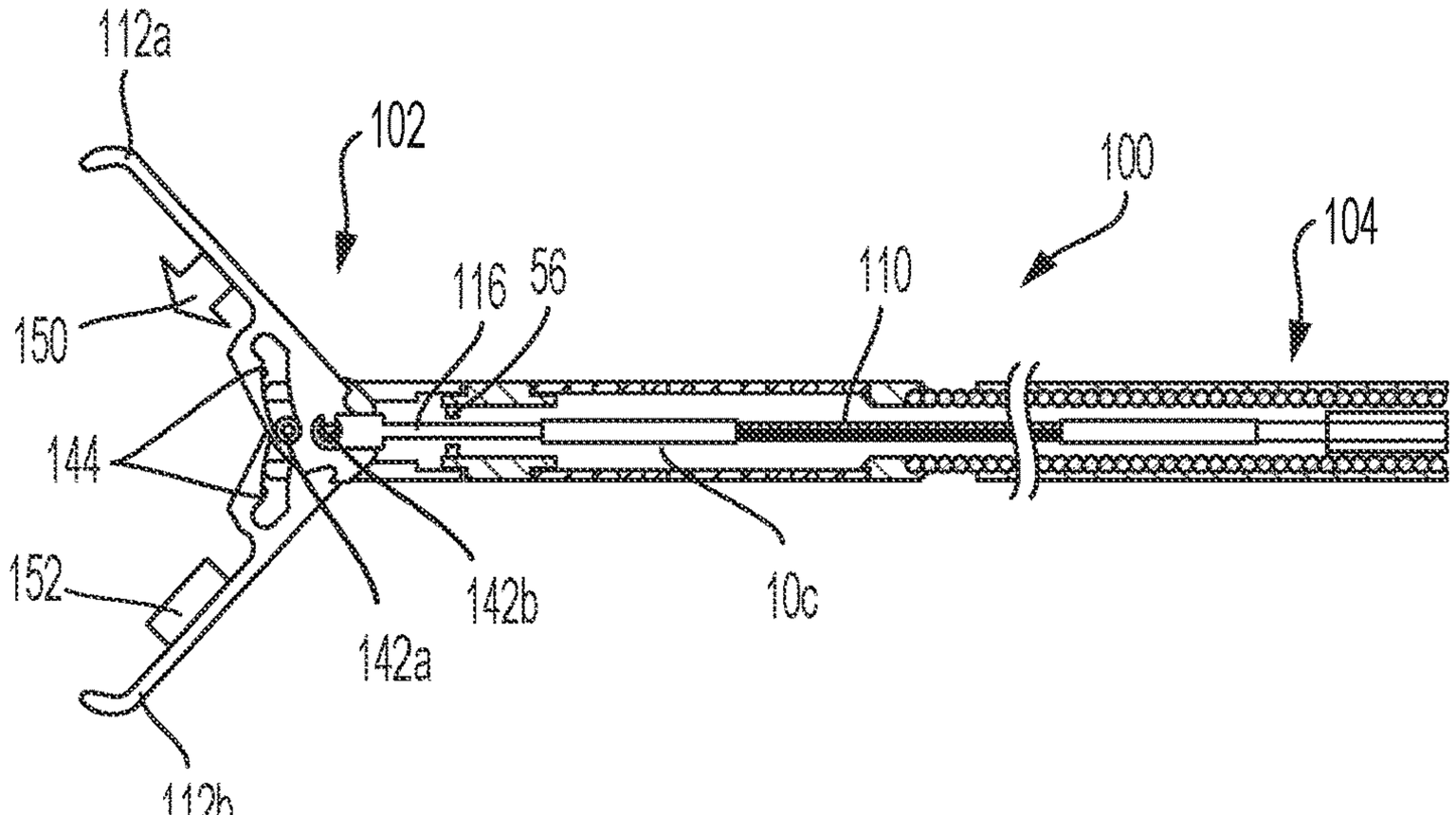

FIG. 21

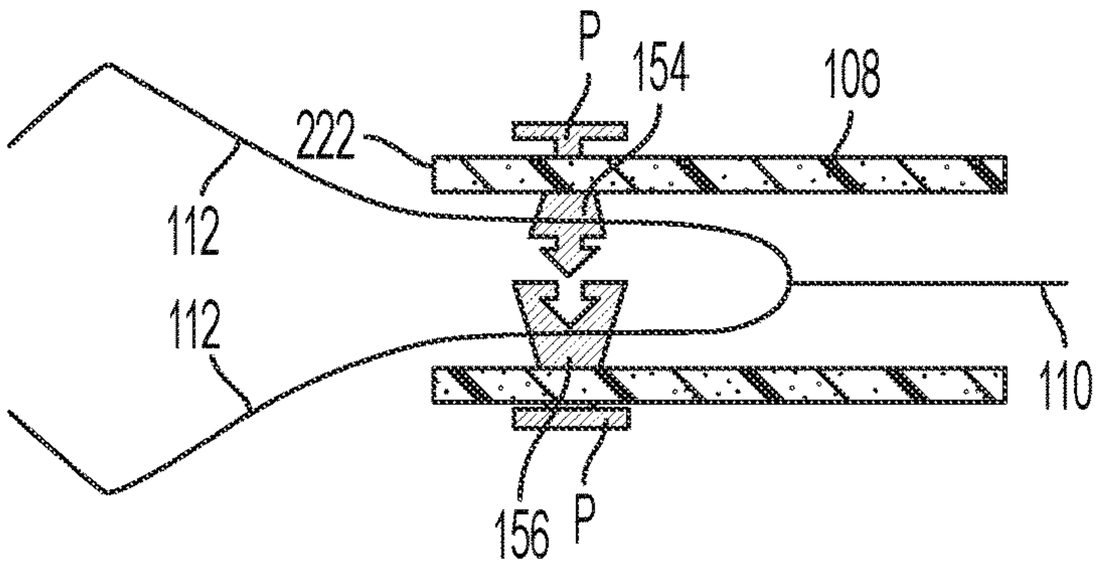

FIG. 22A

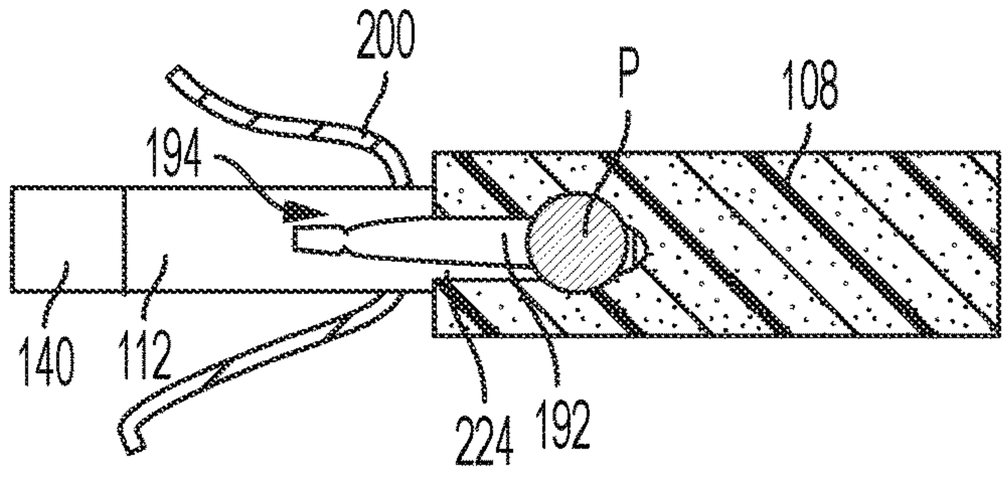

FIG. 22B

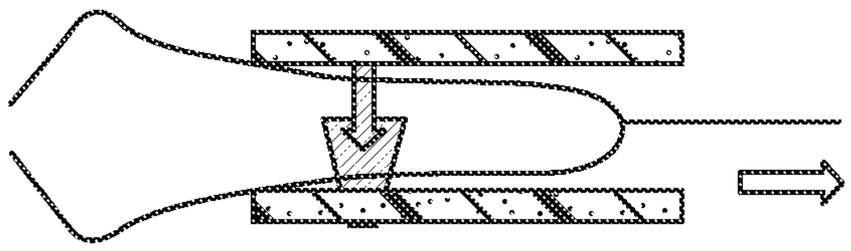

FIG. 22C

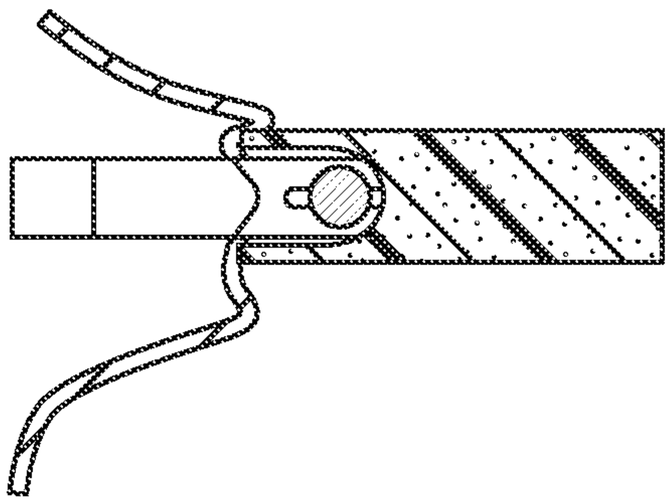

FIG. 22D

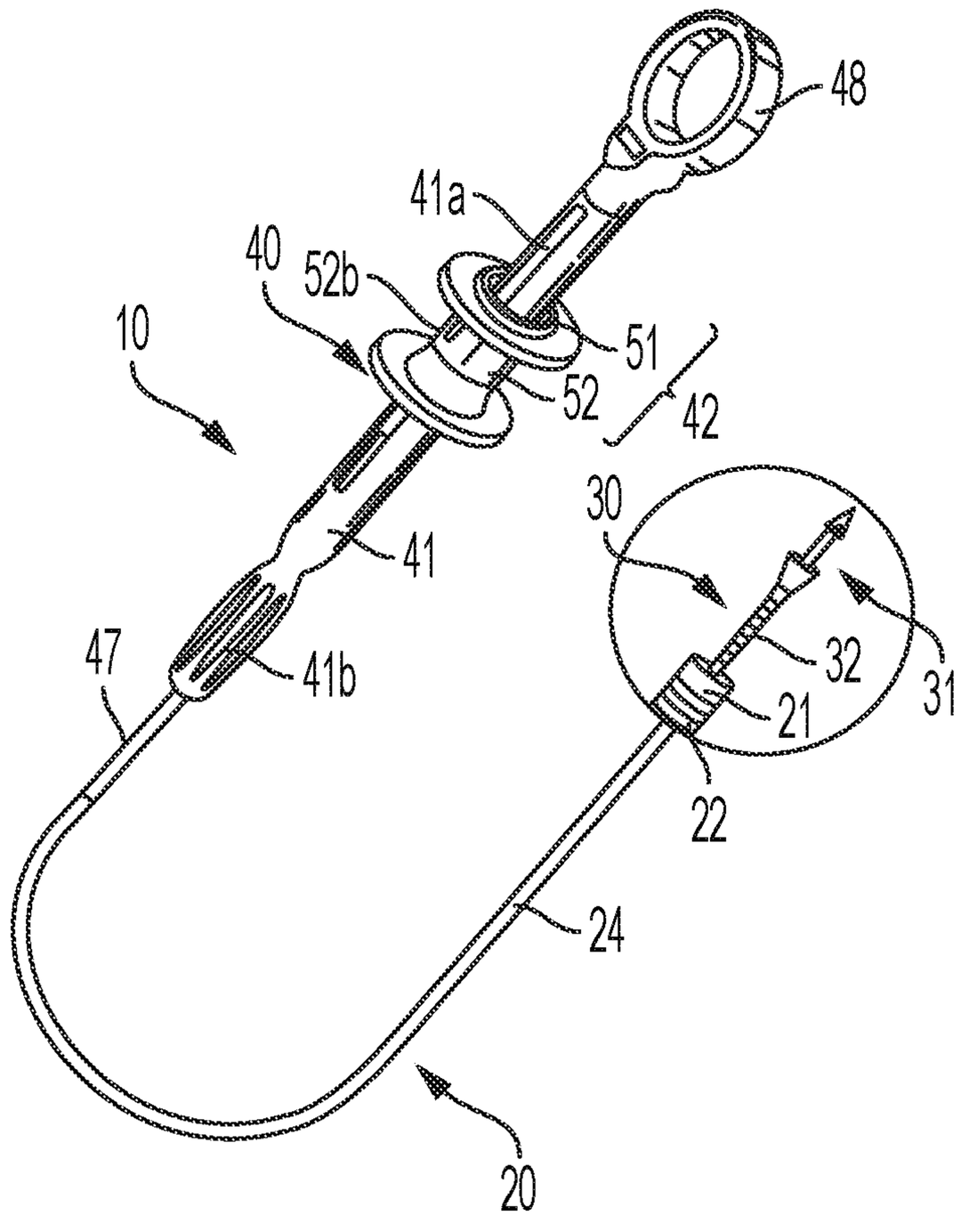
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FIG. 23

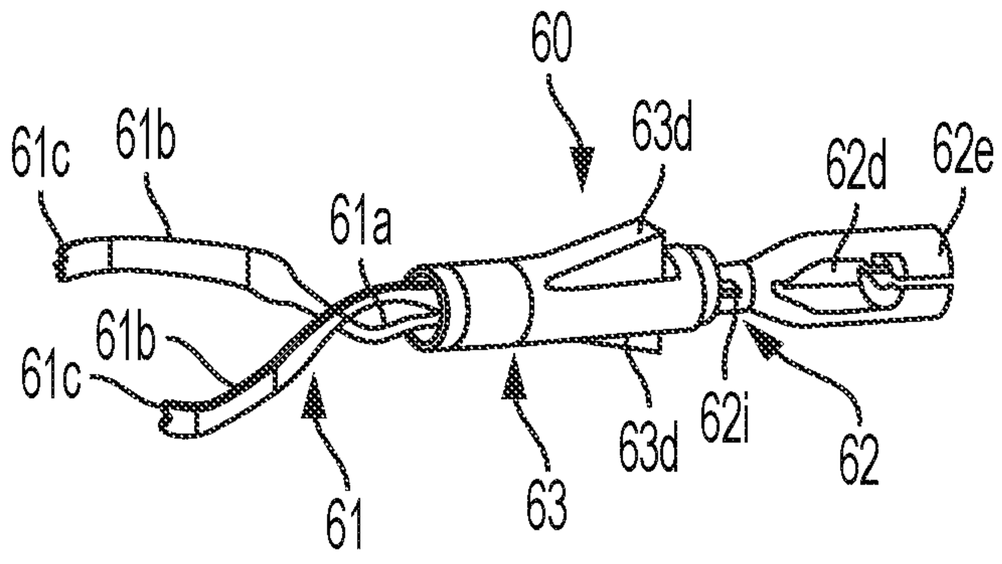
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FIG. 24

CLIP DEVICE FOR ENDOSCOPE

RELATED APPLICATION DATA

This application is based on and claims priority under 35 U.S.C. § 119 to U.S. Provisional Application No. 63/148,655, filed Feb. 12, 2021, the entire contents of which are incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates to a clip device for an endoscope, and more particularly, to an endoscopic clip device with an improved mechanism for locking the clip arms of the clip device.

DESCRIPTION OF THE RELATED ART

Various endoscopic clip devices have been known, many of which require hemostasis clips to control internal bleeding. The hemostasis clips grasp tissue surrounding a wound and hold edges of the wound together temporarily to allow natural healing processes to permanently close the wound. Specialized endoscopic clip devices are used to deliver the hemostasis clips at the desired locations within the body after which the endoscopic clip delivery device is withdrawn, leaving the hemostasis clips within the body. Such a conventional endoscopic clip device may be loaded onto a distal end of an applicator assembly prior to an endoscopic procedure. Once a hemostasis clip has been deployed at a desired target area in the body, the applicator assembly may be reloaded with a new clip unit.

The conventional endoscopic clip device includes a pair of clip arms, proximal ends of which are connected to a connector that is configured to releasably engage a distal end of a control member of an applicator. The clip arms include respective locking mechanisms to lock the clip arms when a target tissue is gripped, such that the clip arms may be drawn toward one another until the locking mechanisms engage one another. Once the clip arms have been locked, a proximal force beyond a predetermined threshold value may be exerted on the control member, disengaging the control member from the connector so that the control member may be coupled to a new clip unit.

However, the locking mechanisms of the conventional endoscopic clip device are deficient in one or more ways. For example, when the conventional locking mechanisms are moved to lock the clip arms, the target tissue may be pinched between the locking mechanisms. In this situation, the locking mechanism cannot function properly, thereby causing an undesirable hemostasis procedure.

SUMMARY OF THE INVENTION

Accordingly, the present disclosure is directed to an endoscopic clip device and clip unit, which substantially obviate one or more of the issues due to limitations and disadvantages found in conventional endoscopic clip devices and clip units.

An object of the present disclosure is to provide a clip device, which comprises a sheath having a lumen with at least one open end and a plurality of clip arms movable between a first configuration in which the plurality of clip arms are opened to receive a target tissue, and a second configuration in which the plurality of clip arms are closed to grip the target tissue. Locking mechanisms respectively provided on the plurality of clip arms engage one another for

maintaining the second configuration. A restraining mechanism is optionally configured to be associated with the locking mechanisms to prevent the target tissue from being pinched between the locking mechanisms.

Another object of the present disclosure is to provide an endoscopic clip device system for treating tissue, which comprises a clip unit including a pair of clip arms, a proximal end of the clip arms connected to a connector, the clip unit movable between a first configuration, in which distal ends of the clip arms are separated from one another to receive a target tissue therebetween, and a second configuration, in which the target tissue is gripped by the clip arms; locking mechanisms respectively disposed on the clip arms for locking the clip arms in the second configuration; an applicator including a sheath and a control member extending therethrough, the sheath extending from a proximal end to a distal end and including a lumen extending therethrough, the control member extending from a proximal end to a distal end configured to be releasably coupled to the connector to move the clip unit between the first configuration and the second configuration, the clip arms being constrained toward the second configuration via a surface of the lumen when the clip arms are drawn proximally thereinto; and a restraining structure configured to operate associated with the clip unit to prevent the target tissue from being pinched between the locking mechanisms.

Still another object of the present disclosure is to provide a method of delivering an endoscopic clip device, which comprises loading a first clip unit on an applicator by coupling a control member of the applicator to a connector at a proximal end of clip arms of the first clip unit; inserting the first clip unit to a target site within a patient via a channel of an endoscope; moving the first clip unit between a first configuration, in which distal ends of the clip arms are separated from one another, and a second configuration, in which the distal ends of the clip arms are drawn toward one another, by moving the control member longitudinally until a target tissue is gripped between the distal ends of the clip arms; locking the clip arms in the second configuration by drawing the control member further proximally until the clip arms engage one another via a locking mechanism thereof; and releasing the first clip unit from the applicator by drawing the control member even further proximally until a proximal force exerted on the connector by the control member exceeding a predetermined threshold value so that the control member disengages from the connector to release the clip assembly from the applicator, wherein, in the second configuration, when the clip arms are drawn toward one another, a restraining mechanism is operated to prevent the target tissue from being pinched between the locking mechanisms.

Additional features and advantages will be set forth in the description that follows, and in part will be apparent from the description, or may be learned by practice of the invention. The objectives and other advantages of the disclosed an endoscopic clip device, system and method will be realized and attained by the structure particularly pointed out in the written description and claims thereof as well as the appended drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

The following detailed description of preferred embodiments can be read in connection with the accompanying drawings in which like numerals designate like elements.

FIG. **1** shows a perspective view of a system according to an exemplary embodiment of the present invention.

FIG. **2** shows a side view of a distal portion according to the system of FIG. **1**.

FIG. **3** shows a side view of an applicator according to the system of FIG. **1**.

FIG. **4** shows a side view of a distal portion of the applicator of FIG. **3**.

FIG. **5** shows a longitudinal cross-sectional view of the distal portion of FIG. **4**.

FIG. **6** shows a perspective view of a portion of the applicator of FIG. **3**.

FIG. **7** shows a longitudinal cross-sectional view of the portion of the applicator of FIG. **6**.

FIG. **8**A is a front view schematically illustrating a clip unit in a first configuration in which a pair of clip arms are opened to receive a target tissue according to an exemplary embodiment, FIG. **8**B is a magnified cross-sectional view taken line A-A of FIG. **8**A, FIG. **8**C is a front view schematically illustrating a clip unit in the first configuration in which restraining members are located on the pair of clip arms more proximally than locking members according to an exemplary embodiment, FIG. **8**D is a perspective view schematically illustrating an exemplary structural arrangement between restraining members and locking members, and FIG. **8**E is a perspective view schematically illustrating another exemplary structural arrangement between restraining members and locking members.

FIG. **9**A is a front view schematically illustrating a clip unit in a second configuration in which the target tissue is gripped by the pair of clip arms are according to an exemplary embodiment, and FIG. **9**B is a magnified cross-sectional view taken line B-B of FIG. **9**A.

FIG. **10**A is a front view schematically illustrating a clip unit in a first configuration in which a pair of clip arms are opened to receive a target tissue according to another exemplary embodiment, and FIG. **10**B is a magnified cross-sectional view taken line C-C of FIG. **10**A.

FIG. **11**A is a front view schematically illustrating a clip unit in a second configuration in which the target tissue is gripped by the pair of clip arms are according to another exemplary embodiment, and FIG. **11**B is a cross-sectional view taken line D-D of FIG. **11**A.

FIGS. **12**A-**12**B show side views of distal portions of additional exemplary embodiments of a clip device system related to the first embodiment.

FIG. **13**A is a front view schematically illustrating a clip unit in a first configuration in which a pair of clip arms are opened to receive a target tissue according to a further exemplary embodiment, and FIG. **13**B is a front view schematically illustrating a clip unit in a second configuration in which the pair of clip arms are closed and grip the target tissue.

FIG. **14**A is a front view schematically illustrating a clip unit in a first configuration in which a pair of clip arms are opened to receive a target tissue according to another exemplary embodiment, and FIG. **14**B is a magnified cross-sectional view taken line E-E of FIG. **14**A.

FIG. **15**A is a front view schematically illustrating a clip unit in a first configuration in which a pair of clip arms are opened to receive a target tissue according to another exemplary embodiment, and FIG. **15**B is a magnified cross-sectional view taken line F-F of FIG. **15**A.

FIG. **16** is a view schematically illustrating a clip unit with a restraining rail that is inserted into a channel of an endoscope according to an exemplary embodiment.

FIG. **17** a view schematically illustrating a clip unit with a restraining rail that is in a first configuration according to an exemplary embodiment.

FIG. **18** shows a side view of a distal portion of an additional exemplary embodiment of a clip device system related to the second embodiment.

FIG. **19**A is a front view schematically illustrating a clip unit in a first configuration in which a pair of clip arms are opened to receive a target tissue according to an exemplary embodiment, FIG. **19**B is a side view schematically illustrating the clip unit of FIG. **19**A, FIG. **19**C is a side view schematically illustrating the clip unit of FIG. **19**A when the clip unit is drawn into a sheath toward a second configuration, and FIG. **19**D is a side view schematically illustrating the clip unit of FIG. **19**A when the clip unit is the second configuration.

FIG. **20**A is a front view schematically illustrating a clip unit in a first configuration in which a pair of clip arms are opened to receive a target tissue according to one exemplary embodiment, FIG. **20**B is a front view schematically illustrating a clip unit in a second configuration in which a pair of clip arms are closed to grip the target tissue, and FIG. **20**C is a front view schematically illustrating a clip unit in the first configuration according to another exemplary embodiment that is different from the one in FIG. **20**A.

FIG. **21** shows a side view of a distal portion of an additional exemplary embodiment of a clip device system related to the third embodiment.

FIG. **22**A is a side view schematically illustrating a clip unit in a first configuration in which a pair of clip arms are opened according to a still further exemplary embodiment, FIG. **22**B is a top view schematically illustrating the clip unit of FIG. **22**A, FIG. **22**C is a side view schematically illustrating the clip unit in a second configuration in which the pair of clip arms are closed, and FIG. **22**D is a top view schematically illustrating the clip unit of FIG. **22**C.

FIG. **23** is a perspective view schematically illustrating an applicator of an endoscope using a clip unit according to one exemplary embodiment.

FIG. **24** is a perspective view schematically illustrating the clip unit to be associated with the applicator of FIG. **23**.

Throughout all of the drawings, dimensions of respective constituent elements are appropriately adjusted for clarity. For ease of viewing, in some instances only some of the named features in the figures are labeled with reference numerals.

DETAILED DESCRIPTION

Hereinafter, accompanying drawings, which are incorporated in and constitute a part of the specification, illustrate exemplary embodiments of the invention, and together with the general description given above and the detailed description of the exemplary embodiments given below, serve to explain the principles of the invention.

Also, it should be noted that the terms "proximal" and "proximally" as used herein, are intended to refer to a direction toward (proximal/proximally) a user of the device, and the terms "distal" and "distally" as used herein, are intended to refer to a direction away from (distal/distally) the user of the device. The term "patient," as used herein, comprises any and all organisms and includes the term "subject." A patient can be a human or an animal.

FIG. **1** shows a perspective view of an exemplary clip device system **100** and FIG. **2** shows a side view of a distal portion of the exemplary clip device system **100**. As shown in FIGS. **1** and **2**, the clip device system **100** comprises a clip unit **102**, an applicator **104** and a cartridge **106**. The clip unit **102** is loadable into a distal portion of the applicator **104** before the system **100** is inserted into a living body to clip

a target tissue. The applicator **104** is configured such that, after deployment of the clip unit **102** in the body of a patient, a new clip unit **102** may be loaded onto the applicator **104** so that the same applicator **104** may be used to deliver a new clip unit **102** to a second portion of the target tissue in the patient. Each clip unit **102** according to this embodiment may be stored in the cartridge **106**, which facilitates loading of the clip unit **102** onto the applicator **104**.

Specifically, as shown in FIG. **1**, prior to being loaded on the applicator **104**, the clip unit **102** is stored in the cartridge **106**, which may be configured, for example, as a storage container so that the clip unit **102** may be securely stored therein. In one embodiment, the clip unit **102** may be stored in the cartridge **106** in a first configuration (tissue receiving configuration). The cartridge **106** includes a proximal opening **174** through which a distal portion of the applicator **104** (e.g., a distal end of the control member **110** and a distal end of the sheath **108**) may be inserted into the cartridge **106** to load the clip unit **102** thereon. Once the distal end **118** of the control member **110** has been coupled to the connector **116** of the clip unit **102**, the clip unit **102** may be drawn toward a second configuration (tissue gripping configuration) to remove the clip unit **102** from the cartridge **106**.

The applicator **104** includes a sheath **108** at a distal end thereof and a control member **110** extending therethrough. The clip unit **102** includes a pair of clip arms **112** including a proximal end **114** connected to a connector **116** that is configured to releasably engage a distal end **118** of the control member **110**. Once the clip unit **102** has been connected to the control member **110**, the clip unit **102** may be moved with respect to the sheath **108** between a first configuration, which is a tissue receiving configuration in which the pair of clip arms **112** are opened to receive a target tissue, and a second configuration, which is a tissue gripping configuration in which the target tissue is gripped by the pair of clip arms **112**.

As shown in FIGS. **3-7**, the applicator **104** includes the sheath **108**, a flexible member **120** extending proximally therefrom, and the control member **110** extending through the sheath **108** and the flexible member **120**. A proximal end of the flexible member **120** is connected to a handle member **122**, which includes an actuator such as, for example, a spool **124**, coupled thereto. In one example, the spool **124** is connected to a proximal end **126** of the control member **110** so that, once the clip unit **102** is loaded onto the applicator **104**, the spool **124** may be slid longitudinally over the handle member **122** to move the clip unit **102** between the first configuration (tissue receiving configuration) and the second configuration (tissue gripping configuration). Specifically, sliding the spool **124** over the handle member **122** moves the control member **110**, and thereby the clip unit **102**, relative to the sheath **108** to move the clip unit **102** between the first and second configurations.

In one embodiment, as shown in FIGS. **6-7**, the handle member **122** includes a positioning feature **128** interfacing with the spool **124** to provide tactile feedback to a user of the exemplary clip device system **100** regarding a position of the connector **116** with respect to the sheath **108**. The positioning feature **128** may include a deformable protrusion extending laterally outward from an exterior surface therefrom. The protrusion is deformable so that the spool **124** may be slid thereover when a force exerted thereon exceeds a predetermined threshold value. The spool **124** may be slid thereover during initial loading of the clip unit **102**. However, when a distal surface **130** of the spool **124** abuts a portion of the protrusion, the positioning feature **128** provides a tactile feedback to the user indicating that the connector **116** is at a distal-most position with respect to the sheath **108**, without extending entirely distally past the sheath **108**. In other words, the clip unit **102** is at a maximum open configuration without extending entirely out of the sheath **108** (e.g., separated from the sheath **108**).

Moreover, a part of the handle member **122** may be cut off to form a recess portion, and a lid member **129**, which is a roof-shaped cover, may be detachably fit into the handle member **122** to cover the recess portion. The lid member **129** has a projection **129***a* formed at a proximal end of the lid member **129**. The projection **129***a* is configured to engage with the positioning feature **128** so that the lid member **129** is prevented from coming off the handle member **122**.

The flexible member **120** (e.g. in FIGS. **1** and **3**) may be formed as a coil of wire through which the control member **110** extends from the distal end **118** to the proximal end **126**. As would be understood by those skilled in the art, the coil of wire preferably has sufficient flexibility to be passed through even tortuous paths of living body and, in this exemplary embodiment, is sized and shaped to permit it to be passed through a channel of an endoscope or other insertion device. Although the flexible member **120** is shown and described as a coil of wire, it will be understood by those of skill in the art that any other suitable flexible structure may be employed so long as the flexible member **120** is capable of providing a force in compression sufficient to counter the tension to be placed on the control member **110** from the clip unit **102**. Although the applicator **104** is described as including the spool **124**, the applicator **104** may include any of a variety of actuating mechanisms for moving the control member **110** to control movement of the clip arms **112**.

The control member **110** extends from the distal end **118** releasably coupled to the connector **116** to the proximal end **126** connected to the spool **124**. The distal end **118** is sized and shaped to be releasably coupled to a corresponding feature of the connector **116**. In one embodiment, the distal end **118** may be shaped as an enlarged ball that is received within a correspondingly shaped socket of the connector **116**. It will be understood by those of skill in the art, however, that the distal end **118** may have any of a variety of shapes and sizes so long as the distal end **118** is releasably coupleable with the connector **116**.

As shown in FIG. **2**, the connector **116** includes a distal end **148** connected to the proximal end **114** and extends proximally therefrom to receive the distal end **118** of the control member **110** therein. The connector **116** includes a longitudinal slot **160** defined via opposed portions **162** that are spreadable to receive the distal end **118** of the control member **110**. The longitudinal slot **160** extends from a proximal opening **164** to a space **166** sized and shaped to receive the distal end **118**. In one exemplary embodiment, the distal end **118** may be configured as a ball received within a correspondingly sized and shaped socket of the space **166**. The proximal opening **164** of the slot **160** has a smaller cross-sectional area (e.g., diameter) than a cross-sectional area of the space **166**. The opposed portions **162** are spreadable to receive the distal end **118** of the control member **110** and biased toward one another so that, once the distal end **118** passes distally into the space **166**, the opposed portions **162** spring back to lock the distal end **118** within the space **166**, coupling the control member **110** to the connector **116**. Thus, longitudinal movement of the control member **110** relative to the sheath **108** may control movement of the clip arms **112** between the tissue receiving and the tissue clipping configurations.

According to this embodiment, the distal end **118** of the control member **110** may be inserted into the connector **116** via the proximal opening **164**. When the control member **110** is pushed distally into the connector **116** beyond a predetermined threshold value, the proximal opening **164** of the longitudinal slot **160** deforms to permit the distal end **118** to be passed through the proximal opening **164** into the space **166**. In one embodiment, opposed portions **162** defining the longitudinal slot **160** may be separated from one another to permit the distal end **118** to be passed through the proximal opening **164** into the space **166**. Once the distal end **118** is received within the space **166**, the longitudinal slot **160** reverts to its original size, holding the distal end **118** of the control member **110** therein.

As shown in FIGS. **4** and **5**, the sheath **108** extends longitudinally from a proximal end **132** connected to a distal end **134** of the flexible member **120** to a distal end **136** and including a lumen **138** extending therethrough. The lumen **138** may be sized and shaped to receive at least a portion of the clip unit **102** therein. The lumen **138** includes a shoulder **176** along a proximal portion thereof which reduces a cross-sectional area of the lumen **138** proximally thereof so that, the connector **116** is prevented from passing proximally past the shoulder **176**. The sheath **108** may be configured as a hypotube attached to the distal end **134** of the flexible member **120**. The sheath **108** may be laser cut to increase a flexibility thereof. For example, the sheath **108** may include a helically extending cut therealong so that the sheath **108** may be flexed along a length thereof. Moreover, the sheath **108** may be such a coil sheath that is configured to include a PTFE tube provided between the coil sheath and stranded wires of multiple metal wires inserted through the sheath **108**. The stranded wires of multiple metal wires may be coated by silicon as a lubricant.

As shown in FIG. **2**, the clip unit **102** includes the pair of clip arms **112**, which have a proximal end **114** connected to the connector **116**. In one embodiment, the pair of clip arms **112** may be formed of a single piece of material bent in half at the proximal end **114** to form the two clip arms **112**. The connector **116** may be connected to the single piece of material at the point at which the material bends (e.g., the proximal end **114**) to form the two clip arms **112**. Although the clip arms **112** are described and shown as being formed of the single piece of material, the pair of clip arms **112** may be formed via two separate pieces of material, proximal ends of which are connected to one another via the connector **116**.

The clip arms **112** of this embodiment are biased so that distal ends **140** thereof move apart from one another into an open tissue receiving configuration when not drawn into the sheath **108**. When drawn into the sheath **108**, the sheath **108** constrains the clip arms **112**, holding the distal ends **140** thereof together in a closed tissue gripping configuration. The connector **116** is longitudinally slidable with the lumen **138** of the sheath **108** to move the clip arms **112** between the tissue receiving configuration and the tissue gripping configuration. The distal ends **140** of each of the clip arms **112** may project laterally inward toward the distal end **140** of the other of the clip arms **112** to facilitate gripping of target tissue therebetween. The distal ends **140** may further include other gripping features such as, for example, teeth and/or protrusions.

The clip arms **112** may include locking mechanisms to lock the pair of clip arms when the clip unit **102** is in the closed tissue gripping configuration. In this exemplary embodiment, as shown in FIG. **2**, the locking mechanisms include corresponding mating features **150**, **152** (a pair of locking members) for locking the clip arms **112** in the closed tissue gripping configuration. A first one of the clip arms **112** includes a male lock feature **150** while a second one of the clip arms **112** includes a female lock feature **152**. In particular, the male lock feature **150** is disposed on and extends from an inner surface of the first one of the clip arms **112** toward the second one of the clip arms **112** and includes a pair of prongs. The female mating feature **152** is disposed on and extends from an inner surface of the second one of the clip arms **112** toward the first one of the clip arms **112**. The female mating feature **152** includes an opening that is sized and shaped to permit the pair of prongs to be received therein.

Additionally, on each arm, the restraining mechanism and the locking mechanism extend in a direction away from the arm different distances. For example and as shown in FIG. **2**, restraining member **181** of the restraining mechanism extends a first distance d**1** in a first direction away from the first arm **112***a* and mating feature **150** of the locking mechanism extends a second distance d**2** in the first direction away from the first arm **112***a*, and the first distance d**1** is greater than the second distance d**2**.

The pair of prongs are deformable, and once the pair of prongs pass through the opening, the pair of prongs revert to their original configuration, locking the male locking member **150** within the female locking member **152**. The male and female locking members **150**, **152** are specifically configured so that the male and female locking members **150** and **152** engage one another only when the pair of clip arms **112** are drawn toward one another beyond a predetermined threshold distance. Thus, the pair of clip arms **112** may be moved between the tissue receiving and tissue gripping configurations multiple times, as desired, prior to locking of the clip unit **102** in the tissue gripping configuration.

Although the clip unit **102** is described as including the above locking mechanisms **150** and **152**, it will be understood by those of skill in the art that a clip unit of the present disclosure may include any of a variety of corresponding mating features for locking the clip arms relative to one another.

The clip unit **102** further includes a restraining mechanism which is operated associated with the locking mechanisms and configured to prevent the target tissue from being pinched between the locking mechanisms when the clip unit **102** is drawn into the sheath **108** to close the pair of clip arms **112** toward the closed tissue gripping configuration. As will be described in details below, the restraining mechanism may have different configurations and may be disposed with different position relationships with respect to the locking mechanisms, as long as the restraining mechanism is configured to be suitable to prevent the target tissue to be pinched between the locking mechanisms.

First Embodiment

FIG. **8**A schematically illustrates a clip unit in a first configuration in which a pair of clip arms are opened to receive a target tissue according to a first exemplary embodiment, and FIG. **8**B is a cross-sectional view taken line A-A of FIG. **8**A. In the first exemplary embodiment, the clip unit **102** includes a restraining mechanism mounted on the pair of clip arms **112**. Specifically, the restraining mechanism includes a first restraining member **181** and a second restraining member **182**. The first restraining member **181** is disposed on and extends from an inner surface of a first one of the clip arms **112** toward a second one of the clip arms **112**. The second restraining member **182** is disposed on and extend from an inner surface of the second one of the clip

arms **112** toward the first one of the clip arms **112**. The restraining first and second members **181** and **182** may be located more distally than the locking members **150** and **152**, respectively. Alternatively, the restraining members **181** and **182** may be attached to the distal end sides of the locking members **150** and **152**, respectively.

Moreover, as shown in FIG. **8**C, the first restraining member **181** and the second restraining member **182** may be respectively located on the pair of clip arms **112** more proximally than the locking members **150** and **152**. In this situation, a distal end portion of the first restraining member **181***a* and a distal end portion of the second restraining member **182***a* should be positioned more distally than the locking members **150** and **152**, respectively. FIG. **8**D is a perspective view schematically illustrating an exemplary structural arrangement between the restraining members **181** and **182** and the locking members **150** and **152**. As shown in FIG. **8**D, each of the restraining members **181** and **182** may include an opening that is sized and shaped for a corresponding one of the locking members **150** and **152** to extend from the inner surface of one of the clip arms **112** through the opening without interfering with the corresponding one of the restraining members **181** and **182**. FIG. **8**E is a perspective view schematically illustrating another exemplary structural arrangement between the restraining members **181** and **182** and the locking members **150** and **152**. As shown in FIG. **8**E, the locking members **150** and **152** may be each attached to two sides of the respective clip arms **112** so that the restraining members **181** and **182** each extend passing through the respective locking members **150** and **152** in a distal direction without interfering with the respective locking members **150** and **152**.

As described above, when the clip unit **102** is in the first configuration, the pair of clip arms **112** are opened to receive the target tissue **200**. As will be described in detail below, the first and second restraining members **181** and **182** are sized and shaped to prevent the target tissue **200** from being pinched between the locking mechanisms **150** and **152** when the pair of clip arms **112** are moved to close and grip the target tissue **200**.

In this exemplary embodiment, the first and second restraining members **181** and **182** are each configured as a curved bar, which may have a flat/round front end surface that comes to contact with the target tissue **200** without hurting the target tissue **200**, when the pair of clip arms **112** are moved to receive and grip the target tissue **200**. The invention is not limited to the flat/round shape for the front end surface. The front end surface of each of the restraining members **181** and **182** may have any suitable protection shape that can minimize or prevent the restraining member **181** and **182** from causing unwanted damage to the target tissue **200**. Additionally, when the restraining members **181** and **182** are configured as a curved bar, the curvature can be such that the distal ends of the restraining members (i.e., the end not attached to the clip arms **181**, **182**) can be toward the distal end of the clip unit **102** (i.e., toward the opening through which the target tissue **200** is received by the clip unit **102**) or can be toward the proximal end of the clip unit **102** (i.e., toward proximal end **114** connected to a connector **116**).

The first and second restraining members **181** and **182** may be formed of the same single piece of material that is employed to form the pair of clip arms **112** as noted above. Alternatively, the pair of restraining members **181** and **182** may be formed of a different material from the pair of clip arms **112** and thus are attached to the pair of clip arms **112** during an assembly process by an adhesive substance or soldering.

The first and second restraining members **181** and **182** may be made of any suitable biocompatible materials, such as, but not limited to, polymeric polymers and materials, including fillers such as metals, carbon fibers, glass fibers or ceramics, and combinations thereof. The metals may include cobalt chrome alloy, nickel titanium alloy, titanium, stainless steel, and the like. Useful, but non-limiting, polymeric materials include polyethylene, polypropylene, polyvinyl chloride, polytetrafluoroethylene, fluorinated ethylene propylene copolymer, polyvinyl acetate, polystyrene, polyethylene terephthalate), naphthalene dicarboxylatε derivatives, such as polyethylene naphthalate, polybutylene naphthalate, polytrimethylene naphthalate and trimethylenediol naphthalate, polyurethane, polyurea, silicone rubbers, polyamides, polycarbonates, polyaldehydes, natural rubbers, polyester copolymers, styrene-butadiene copolymers, polyethers, fully or partially halogenated polyethers, polyamidc/polyether polyesters, and copolymers and combinations thereof, and ABS (acrylonitrile butadiene styrene copolymer), PEEK (Poly Ether Ether Ketone), etc.

FIG. **9**A is a front view schematically illustrating a clip unit in a second configuration in which the target tissue is gripped by the pair of clip arms are according to the first exemplary embodiment, and FIG. **9**B is a cross-sectional view taken line B-B of FIG. **9**A. Once the target tissue **200** is received between the clip arms **112** as shown in FIG. **8**A, the clip assembly **102** is moved toward the second configurator, in which the target tissue **200** is gripped by the pair of clip arms **112**, by moving the control member **110** proximally relative to the clip assembly **102**. With the pair of clip arms **112** are closed to each other, the first and second restraining members **181** and **182** are moved to contact each other and are deformed to extend distally, thereby pushing the target tissue away from the locking mechanisms **150** and **152**. As shown in FIG. **93**, the restraining members **181** and **182** contact each other and form a stopping bar in front of the locking mechanisms **150** and **152**. The stopping bar formed by the restraining members **181** and **182** is able to stop die target tissue **200** from entering into an area between the locking mechanisms **150** and **150**, thereby preventing the target tissue **200** from being pinched therebetween.

Also, the restraining members **181** and **182** may be made flexible and deformable (i.e., movable toward one another). When the pair of clip arms **112** are closed further to each other, as shown in FIG. **9**A, the stopping bar formed by the restraining members **181** and **182** is moved further distally to keep the target tissue away from the locking mechanisms **150** and **152**.

When it is confirmed that a desired portion of the target tissue **200** is gripped between the clip arms **112** (e.g., portions of tissue on opposite sides of a bleeding wound), the control member **110** is drawn further proximally relative to the clip assembly **102** (via the spool **124**) to lock the clip assembly **102** in the closed configuration. That is, the clip arms **112** are drawn further proximally into the sleeve **1088** until the locking mechanisms **150**, **152** engage one another, locking the clip arms **112** relative to one another.

FIG. **10**A is a front view schematically illustrating a clip unit in a first configuration in which a pair of clip arms are opened to receive a target tissue according to another exemplary embodiment, and FIG. **10**B is a cross-sectional view taken line C-C of FIG. **10**A. FIG. **11**A is a front view schematically illustrating a clip unit in a second configuration in which the target tissue is gripped by the pair of clip

arms are according to another exemplary embodiment, and FIG. **11**B is a cross-sectional view taken line D-D of FIG. **11**A.

In this modified exemplary embodiment, as shown in FIG. **10**B, the restraining member **181** is disposed on the first one of the clip arms **112** at a position different from a position where the restraining member **182** is disposed on the second one of the clip arms **112**. Thus, the restraining members **182** and **182** do not contact each other even when the clip unit **102** is drawn toward the second configuration in which the pair of clip arms **112** are closed to grip the target tissue **200**. As shown in FIGS. **11**A and **111**B, the restraining member **181** and **182** cross each other in the second configuration, in which each of the restraining member **181** and **182** serves as a stopping bar (anti-intrusion mechanism) to prevent the target tissue **200** from being pinched between the locking mechanisms **150** and **152** when the locking mechanisms **150** and **152** are moved to engage one another.

FIGS. **12**A and **12**B show side views of a distal portion of additional exemplary embodiments of a clip device system related to the first embodiment. The clip delivery system **100** includes a clip unit **102** attached to distal end of an applicator **104**. For example, clip unit **102** can be connected to a control member **110** via a connector **116**. The control member **110** is movable within a plenum of the applicator **104** and manipulation of the control member **110**, e.g., retracting and extending, moves the clip unit **102** to be withdrawn into at least a portion of the passage **10***c* or extended out from an opening at the distal end of the control member **110**. Stop **56** serves to delimit the distance the clip unit **102** can move in the retracting direction.

As shown in FIGS. **12**A and **12**B, the clip unit **102** has two clip arms **112***a*, **112***b* and the bases of the two clip arms **112***a*, **112***b* are pivotable relative to each other about pivot connection **142***a*. In the embodiment shown, a groove or track **144** in the clip arms **112***a*, **112***b* accommodates the movement of the clip arms **112***a*, **112***b* as they move from the open position, i.e., the first configuration, to the closed position, i.e., the second configuration. Additionally, the clip unit **102** is pivotable and/or rotatable relative to the control member **110** about pivot connection **142***b*.

As with other embodiments disclosed herein, each clip arm **112***a*, **112***b* includes locking mechanisms to lock the pair of clip arms when the clip unit **102** is in the closed tissue gripping configuration and the locking mechanisms includes corresponding mating features **150**, **152** (e.g., a pair of locking members—male lock feature **150** and female lock feature **15**) for locking the clip arms **112** in the closed tissue gripping configuration. As with other embodiments disclosed herein, each clip arm **112***a*, **112***b* also includes a restraining mechanism mounted on the pair of clip arms **112***a*, **112***b*. Specifically, the restraining mechanism includes a first restraining member **181** and a second restraining member **182**. Any of the embodiments disclosed herein for the locking mechanisms and restraining mechanism can be utilized in the clip unit **102** of the embodiment shown and described with respect to FIGS. **12**A and **12**B. In some embodiments, the clip unit **102** only includes a restraining mechanism (such as first restraining member **181** and second restraining member **182** as shown in FIG. **12**B), which function to suppress tissue from entering the proximal side of the clip unit **102** and interfering with the pivoting of the clip unit **102**. In other respects, such as other structural features, configuration and operation, the embodiments of the clip unit **102** and clip arms **112***a*, **112***b* in FIGS. **12**A and **12**B can be consistent with the structural features, configuration and operation for the first embodiments describe above with reference to FIGS. **2** to **11**.

Second Embodiment

FIG. **13**A is a front view schematically illustrating a clip unit in a first configuration in which a pair of clip arms are opened to receive a target tissue according to a second exemplary embodiment, and FIG. **13**B is a front view schematically illustrating a clip unit in a second configuration in which the pair of clip arms are closed and grip the target tissue according to the second exemplary embodiment.

In the second exemplary embodiment, the restraining mechanism is a restraining rail **184** that connects the locking mechanism **150** to the locking mechanism **152**. The restraining rail **184** may be shaped as a bar and serves as a stopping bar between the locking mechanisms **150** and **152**. The restraining rail **184** is able to stop the target tissue **200** from entering into an area between the locking mechanisms **150** and **152**, thereby preventing the target tissue **200** from being pinched therebetween.

As shown in FIG. **13**A, the clip unit **102** includes the restraining rail **184**, which has one end attached to a tip end of the locking mechanism **150**, and the other end passing through a through-hole (or slot) formed on the locking mechanism **152**. By this exemplary configuration, the restraining rail **184** serves as a stopping bar that is able to stop the target tissue **200** from entering into an area between the locking mechanisms **150** and **152**, thereby preventing the target tissue **200** from being pinched therebetween.

The one end of the restraining rail **184** may be bonded to the tip of the locking mechanism **150** by an adhesive substance, heating or pressing process. The through-hole may be part of an opening of the locking mechanism **152**, which is sized and shaped to permit the locking mechanism **150** to be received therein and also to permit the restraining rail **184** to be passed therethrough.

As shown in FIG. **13**B, when the clip unit **102** is drawn proximally toward the second configuration, in which the pair of clip arms **112** are closed to grip the target tissue **200**, the restraining rail **184** passes through the opening of the locking mechanism **152**, during which the target tissue **200** is prevented from being pinched by the locking mechanisms **150** and **152** by the restraining rail **184**. Once the locking mechanisms **150** and **152** are engaged to one another, the restraining rail **184** is moved outside the clip unit **102**.

The restraining rail **184** is made of a flexible and deformable material, and may be formed of any suitable biocompatible materials, such as, but not limited to, polymeric polymers and materials, including fillers such as metals, carbon fibers, glass fibers or ceramics, and combinations thereof. The metals may include cobalt chrome alloy, nickel titanium alloy, titanium, stainless steel, and the like. Useful, but non-limiting, polymeric materials include polyethylene, polypropylene, polyvinyl chloride, polytetrafluoroethylene, fluorinated ethylene propylene copolymer, polyvinyl acetate, polystyrene, polyethylene terephthalate), naphthalene dicarboxylatε derivatives, such as polyethylene naphthalate, polybutylene naphthalate, polytrimethylene naphthalate and trimethylenediol naphthalate, polyurethane, polyurea, silicone rubbers, polyamides, polycarbonates, polyaldehydes, natural rubbers, polyester copolymers, styrene-butadiene copolymers, polyethers, fully or partially halogenated polyethers, polyamidc/polyether polyesters,

and copolymers and combinations thereof, and ABS (acrylonitrile butadiene styrene copolymer), PEEK (Poly Ether Ether Ketone), etc.

FIG. **14**A is a front view schematically illustrating a clip unit in a first configuration in which a pair of clip arms are opened to receive a target tissue according to another exemplary embodiment, and FIG. **14**B is a cross-sectional view taken line E-E of FIG. **14**A.

In this modified exemplary embodiment, as shown in FIGS. **14**A and **14**B, a pair of restraining rails **186** each have one end attached to a corresponding side of the locking mechanism **150**, and the other end passing through a corresponding through-hole of the locking mechanism **152**. Or the other end of each of the pair of restraining rails **186** may pass through a groove formed on a corresponding side of the locking mechanism **152** and the second one of the pair of clip arms **112**.

The one end of each of the restraining rails **186** may be bonded to the corresponding side of the locking mechanism **150** by an adhesive substance, heating or pressing process. The corresponding through-hole may be part of an opening of the locking mechanism **152**, which is sized and shaped to permit the locking mechanism **150** to be received therein and also to permit the restraining rails **186** to be passed therethrough. Or, the groove is sized and shaped to permit the restraining rails **186** to be passed through the locking mechanism **152** and the second one of the pair of clip arms **112**.

The invention is not limited to have the pair of restraining rails **186**. The invention may have one single restraining rail **186**, which has its one end attached to one side of the locking mechanism **150**, and its other end passing through a through-hole of the locking mechanism **152**. Or the other end of the single restraining rail **186** may pass through a groove formed on one side of the locking mechanism **152** and the second one of the pair of clip arms **112**.

The restraining rails **186** may be made of a flexible and deformable material, and may be formed of any suitable biocompatible materials, such as, but not limited to, polymeric polymers and materials, including fillers such as metals, carbon fibers, glass fibers or ceramics, and combinations thereof. The metals may include cobalt chrome alloy, nickel titanium alloy, titanium, stainless steel, and the like. Useful, but non-limiting, polymeric materials include polyethylene, polypropylene, polyvinyl chloride, polytetrafluoroethylene, fluorinated ethylene propylene copolymer, polyvinyl acetate, polystyrene, polyethylene terephthalate), naphthalene dicarboxylatε derivatives, such as polyethylene naphthalate, polybutylene naphthalate, polytrimethylene naphthalate and trimethylenediol naphthalate, polyurethane, polyurea, silicone rubbers, polyamides, polycarbonates, polyaldehydes, natural rubbers, polyester copolymers, styrene-butadiene copolymers, polyethers, fully or partially halogenated polyethers, polyamidc/polyether polyesters, and copolymers and combinations thereof, and ABS (acrylonitrile butadiene styrene copolymer), PEEK (Poly Ether Ether Ketone), etc.

FIG. **15**A is a front view schematically illustrating a clip unit in a first configuration in which a pair of clip arms are opened to receive a target tissue according to another exemplary embodiment, and FIG. **15**B is a cross-sectional view taken line E-E of FIG. **15**A.

In this modified exemplary embodiment, as shown in FIGS. **15**A and **15**B, a groove **260** is formed at one side of each of the locking mechanisms **150** and **152**, and a restraining rail **188** has one end attached to the groove **260** of the one locking mechanism **150**, and the other end passing through the groove **260** of the other locking mechanism **152**.

The one end of the restraining rail **188** may be bonded to the groove **260** of the locking mechanism **150** by an adhesive substance, heating or pressing process. The groove **260** is sized and shaped to permit the restraining rail **188** to be passed through the locking mechanism **152** and the second one of the pair of clip arms **112**.

The restraining rail **188** may be made of a flexible and deformable material, and may be formed of any suitable biocompatible materials, such as, but not limited to, polymeric polymers and materials, including fillers such as metals, carbon fibers, glass fibers or ceramics, and combinations thereof. The metals may include cobalt chrome alloy, nickel titanium alloy, titanium, stainless steel, and the like. Useful, but non-limiting, polymeric materials include polyethylene, polypropylene, polyvinyl chloride, polytetrafluoroethylene, fluorinated ethylene propylene copolymer, polyvinyl acetate, polystyrene, polyethylene terephthalate), naphthalene dicarboxylatε derivatives, such as polyethylene naphthalate, polybutylene naphthalate, polytrimethylene naphthalate and trimethylenediol naphthalate, polyurethane, polyurea, silicone rubbers, polyamides, polycarbonates, polyaldehydes, natural rubbers, polyester copolymers, styrene-butadiene copolymers, polyethers, fully or partially halogenated polyethers, polyamidc/polyether polyesters, and copolymers and combinations thereof, and ABS (acrylonitrile butadiene styrene copolymer), PEEK (Poly Ether Ether Ketone), etc.

FIG. **16** is a view schematically illustrating a clip unit with a restraining rail that is inserted into a channel of an endoscope according to an exemplary embodiment, and FIG. **17** a view schematically illustrating a clip unit with a restraining rail that is in a first configuration according to an exemplary embodiment. As shown in FIGS. **16** and **17**, in use, after the clip unit **102** has been loaded onto the applicator **104**, the clip unit **102** in a closed configuration is disposed at the distal end of the sheath **108** and the pair of clip arms **112** projecting out of an open end **222** of the sheath **108** are closed. In this configuration, the clip unit **102** is inserted through a channel **230** of an insertion portion **240** of an endoscope (or any other insertion device) and inserted into the body (e.g., through a natural body lumen) to a site adjacent to a target portion of tissue to be clipped. The restraining rail **184** is connected to the locking mechanisms **150** and **152**, and is deformed to be disposed between the clip unit **102** and an inner surface of the channel **230**. Once the insertion portion **240** arrives the side adjacent to the target portion to be clipped, the clip unit **102** is pushed out of a channel **230** through an endoscope tip **242**, and the pair of clip arms **112** are opened for use.

FIG. **18** shows a side view of a distal portion of an additional exemplary embodiment of a clip device system related to the second embodiment. The clip delivery system **100** includes a clip unit **102** attached to distal end of an applicator **104**. For example, clip unit **102** can be connected to a control member **110** via a connector **116**. The control member **110** is movable within a plenum of the applicator **104** and manipulation of the control member **110**, e.g., retracting and extending, moves the clip unit **102** to be withdrawn into at least a portion of the passage **10***c* or extended out from an opening at the distal end of the control member **110**. Stop **56** serves to delimit the distance the clip unit **102** can move in the retracting direction.

As shown in FIG. **18**, the clip unit **102** has two clip arms **112***a*, **112***b* and the bases of the two clip arms **112***a*, **112***b* are pivotable relative to each other about pivot connection **142***a*.

In the embodiment shown, a groove or track **144** in the clip arms **112***a*, **112***b* accommodates the movement of the clip arms **112***a*, **112***b* as they move from the open position, i.e., the first configuration, to the closed position, i.e., the second configuration. Additionally, the clip unit **102** is pivotable and/or rotatable relative to the control member **110** about pivot connection **142***b*.

As with other embodiments disclosed herein, each clip arm **112***a*, **112***b* includes locking mechanisms to lock the pair of clip arms when the clip unit **102** is in the closed tissue gripping configuration and the locking mechanisms includes corresponding mating features **150**, **152** (e.g., a pair of locking members—male lock feature **150** and female lock feature **15**) for locking the clip arms **112** in the closed tissue gripping configuration. As with other embodiments disclosed herein, one of the clip arms **112***a*, **112***b* also includes a restraining mechanism mounted thereon. Specifically, the restraining mechanism includes restraining rail **184**. Any of the embodiments disclosed herein for the locking mechanisms and restraining mechanism can be utilized in the clip unit **102** of the embodiment shown and described with respect to FIG. **18**. In some embodiments, the clip unit **102** includes a restraining mechanism (such as restraining rail **184** as shown in FIGS. **13**A-B, **14**A-B and **16-17** or restraining rail **188** as shown in FIGS. **15**A-B). In other respects, such as other structural features, configuration and operation, the embodiments of the clip unit **102** and clip arms **112***a*, **112***b* in FIG. **18** can be consistent with the structural features, configuration and operation for the second embodiments describe above with reference to FIGS. **13**A-B to **17**.

Third Embodiment

FIG. **19**A is a front view schematically illustrating a clip unit in a first configuration in which a pair of clip arms are opened to receive a target tissue according to a third exemplary embodiment, FIG. **19**B is a side view schematically illustrating the clip unit of FIG. **19**A, FIG. **19**C is a side view schematically illustrating the clip unit of FIG. **19**A when the clip unit is drawn into a sheath toward a second configuration, and FIG. **19**D is a side view schematically illustrating the clip unit of FIG. **19**A when the clip unit is the second configuration.

In the third exemplary embodiment, the positions of the locking mechanisms **150** and **152** are adjusted such that the locking mechanisms **150** and **152** are disposed more proximally than those in the first and second exemplary embodiments, so that the locking mechanism **150** and **152** are engaged to one another inside the sheath **108**. By this adjustment, the open end **222** of the sheath **108** can serve the restraining mechanism, because the open end is sized and shaped such that the target tissue **200** cannot enter into the sheath **108** through the opening, thereby preventing the target tissue **200** from being pinched between the locking mechanisms **150** and **152**.

As shown in FIGS. **19**A-**19**D, when the clip unit **102** is drawn proximally into the sheath **108**, the pair of clip arms **112** are moved toward the closed configuration. Even if there is a portion of the target tissue **200** that projects in-between the locking mechanisms **150** and **152**, since the locking mechanisms **150** and **152** are adjusted to engage one another inside the sheath **108**, the portion of the target tissue **200** is blocked outside the sheath **108** by the open end **222**.

FIG. **20**A is a front view schematically illustrating a clip unit in a first configuration in which a pair of clip arms are opened to receive a target tissue according to another exemplary embodiment, and FIG. **20**B is a front view schematically illustrating a clip unit in a second configuration in which a pair of clip arms are closed to grip the target tissue.

As shown in FIGS. **20**A and **20**B, the open end **222** of the sheath **108** includes a restraining member **190** (see the boxes I in FIG. **20**A and II in FIG. **20**B) that is a partition member equally dividing the open end **222** into a first opening **222***a* for the first one of the pair of clip arms **112** and a second opening **222***b* for the second one of the pair of clip arms **112**. The first opening **222***a* is sized and shaped to permit the first one of the pair of clip arms **112** and the locking mechanism **150** to pass through, and the second opening **222***b* is sized and shaped to permit the second one of the pair of clip arms **112** and the locking mechanism **152** to pass through. By this configuration, even if there is a portion of the target tissue **200** that projects in-between the locking mechanisms **150** and **152**, since the locking mechanisms **150** and **152** are adjusted to engage one another inside the sheath **108**, the portion of the target tissue **200** is blocked outside the sheath **108** by the restraining member **190**.

FIG. **20**C is a front view schematically illustrating a clip unit in the first configuration according to a modified embodiment of FIG. **20**A. As shown in FIG. **20**C, the open end **222** of the sheath **108** includes two restraining members **191** and **192** (see the boxes III in FIG. **20**C). The restraining member **191** is a bar-shaped member that extends inwardly from the open end **222** toward a center axis "O" of the open end **222**. The restraining member **192** is also a bar-shaped member that extends inwardly from the open end **222** and faces the restraining member **191** without contacting the restraining member **191**. By this configuration, even if there is a portion of the target tissue **200** that projects in-between the locking mechanisms **150** and **152**, since the locking mechanisms **150** and **152** are adjusted to engage one another inside the sheath **108**, the portion of the target tissue **200** can be blocked outside the sheath **108** by the restraining members **190** and **191**.

The restraining member **190** may be integrally formed with the sheath **108**, or may be bonded to the open end **222** by an adhesive substance, heating or pressing process. The restraining members **191** and **192** may also be formed integrally with the sheath **108**, or be respectively attached to an inner surface of the open end **222** by an adhesive substance, heating or pressing process.

The restraining member **190** may be made of any suitable biocompatible materials, such as, but not limited to, polymeric polymers and materials, including fillers such as metals, carbon fibers, glass fibers or ceramics, and combinations thereof. The metals may include cobalt chrome alloy, nickel titanium alloy, titanium, stainless steel, and the like. Useful, but non-limiting, polymeric materials include polyethylene, polypropylene, polyvinyl chloride, polytetrafluoroethylene, fluorinated ethylene propylene copolymer, polyvinyl acetate, polystyrene, polyethylene terephthalate), naphthalene dicarboxylatε derivatives, such as polyethylene naphthalate, polybutylene naphthalate, polytrimethylene naphthalate and trimethylenediol naphthalate, polyurethane, polyurea, silicone rubbers, polyamides, polycarbonates, polyaldehydes, natural rubbers, polyester copolymers, styrene-butadiene copolymers, polyethers, fully or partially halogenated polyethers, polyamidc/polyether polyesters, and copolymers and combinations thereof, and ABS (acrylonitrile butadiene styrene copolymer), PEEK (Poly Ether Ether Ketone), etc.

FIG. **21** shows a side view of a distal portion of an additional exemplary embodiment of a clip device system related to the third embodiment. The clip delivery system

100 includes a clip unit 102 attached to distal end of an applicator 104. For example, clip unit 102 can be connected to a control member 110 via a connector 116. The control member 110 is movable within a plenum of the applicator 104 and manipulation of the control member 110, e.g., retracting and extending, moves the clip unit 102 to be withdrawn into at least a portion of the passage 10*c* or extended out from an opening at the distal end of the control member 110. Stop 56 serves to delimit the distance the clip unit 102 can move in the retracting direction.

As shown in FIG. 21, the clip unit 102 has two clip arms 112*a*, 112*b* and the bases of the two clip arms 112*a*, 112*b* are pivotable relative to each other about pivot connection 142*a*. In the embodiment shown, a groove or track 144 in the clip arms 112*a*, 112*b* accommodates the movement of the clip arms 112*a*, 112*b* as they move from the open position, i.e., the first configuration, to the closed position, i.e., the second configuration. Additionally, the clip unit 102 is pivotable and/or rotatable relative to the control member 110 about pivot connection 142*b*.

As with other embodiments disclosed herein, each clip arm 112*a*, 112*b* includes locking mechanisms to lock the pair of clip arms when the clip unit 102 is in the closed tissue gripping configuration and the locking mechanisms includes corresponding mating features 150, 152 (e.g., a pair of locking members—male lock feature 150 and female lock feature 15) for locking the clip arms 112 in the closed tissue gripping configuration. Any of the embodiments disclosed herein for the locking mechanisms can be utilized in the clip unit 102 of the embodiment shown and described with respect to FIG. 21. In some embodiments, the clip unit 102 includes a locking mechanism as shown in FIGS. 19A-D and 20A-B and does not include a retaining mechanism. In other respects, such as other structural features, configuration and operation, the embodiments of the clip unit 102 and clip arms 112*a*, 112*b* in FIG. 18 can be consistent with the structural features, configuration and operation for the third embodiments describe above with reference to FIGS. 19A-D and 20A-B.

Fourth Embodiment

FIG. 22A is a side view schematically illustrating a clip unit in a first configuration in which a pair of clip arms are opened according to a fourth exemplary embodiment, FIG. 22B is a top view schematically illustrating the clip unit of FIG. 22A, FIG. 22C is a side view schematically illustrating the clip unit in a second configuration in which the pair of clip arms are closed, and FIG. 22D is a top view schematically illustrating the clip unit of FIG. 22C.

In the fourth embodiment, as shown in FIGS. 22A and 22B, the clip unit 102 includes locking mechanisms 154 and 156 that are disposed inside the sheath 108 and positioned more proximally than the open end 222 of the sheath 108. The sheath 108 includes a recess (notch) 224 extending proximally from the open end 222 and having a U-shape. The recess/notch 224 in this invention is not limited to the U-shape, and may be any shape and size that is suitable for the recess/notch 224 to receive the locking mechanisms 154 and 156. The locking mechanisms 154 and 156 are engaged with a groove 192 that is formed on each of the pair of clip arms 112. The locking mechanism 154 and 156 each include a locking pin P that has a diameter larger than a width of the groove 192 so that the locking mechanisms 154 and 156 is slidable along the groove 192 without coming off the pair of clip arms 112.

The groove 192 may be shaped as a taper extending narrowly in the distal direction, and includes a reduced diameter portion 194 at a distal end portion thereof. By this configuration, as shown in FIGS. 22C and 22D, when the clip unit 102 is drawn proximally, the locking pin P moves distally with respect to the pair of clip arms 112 and makes the locking mechanisms 154 and 156 closer to each other. When the locking pin P arrives the reduced diameter portion 194, the locking pin P is locked at the reduced diameter portion 194 so as to prevent the locking mechanisms 154 and 156 from moving with respect to the pair of clip arms 112.

Since the locking mechanisms 154 and 156 are located inside the sheath 108 and more proximally than the open end 222 of the sheath 108, the target tissue 200 cannot enter into the sheath 108 because of the configuration of the open end 222 as described above. Thus, as the target tissue 200 is blocked by the open end 222 from entering into the sheath 108, the target tissue 200 can be prevented from being pinched between the locking mechanisms 154 and 156.

Exemplary Methods

An exemplary method for loading the clip unit 102 housed within the cartridge 106 to the applicator 104 comprises inserting the control member 110 and/or the sheath 108 of the applicator 104 through the proximal opening 174 of the cartridge 106. The distal end 118 of the control member 110 is moved with respect to the cartridge 106 by, for example, moving the spool 124 distally against the connector 116 until a distal force of the distal end 118 against the connector 116 exceeds a predetermined threshold value, deforming the proximal opening 164 of the slot 160 of the connector 116 to permit the distal end 118 to pass therethrough into the space 166 of the connector 116. As the distal end 118 is moved distally with respect to the sheath 108, the spool 124 may slide distally over the positioning feature 128 of the handle member 122, providing tactile feedback to the user that the distal end 118 of the control member 110 has been extended distally past the distal end 136 of the sheath 108 to be coupled to the connector 116. Once the distal end 118 is received within the space 166, the connector 116 reverts to its original shape, holding the distal end 118 therewithin. Upon coupling of the connector 116 and the control member 110, the clip unit 102 has been successfully loaded onto the applicator 104.

To remove the loaded clip unit 102 from the cartridge 106, the clip arms 112 are drawn proximally with respect to the sheath 108 of the applicator 104 to move the clip arms 112 toward the tissue gripping configuration, in which the restraining members 181 and 182 contact and are deform by each other as shown in FIG. 9A or cross each other as shown in FIG. 11A. The spool 124 may be drawn proximally with respect to the handle member 122 until the spool 124 is drawn proximally of the positioning feature 128. As described above, an interior surface of the lumen 138 of the sheath 108 constrains the clip arms 112 as they are drawn thereinto, to move the clip unit 102 toward the tissue gripping configuration. The clip unit 102 may then be drawn out of the cartridge 106 via the opening 174.

In use, after the clip unit 102 has been loaded onto the applicator 104, the clip unit 102 is inserted through the channel 230 (in FIG. 16) of an endoscope (or any other insertion device) and inserted into the body (e.g., through a natural body lumen) to a site adjacent to a target portion of tissue to be clipped. The clip unit 102 is inserted toward the target tissue 200 in the closed configuration to facilitate its passage through the channel 230. Upon reaching the site of the target tissue 200, the clip unit 102 is advanced out of the distal end 42 (in FIG. 17) of the channel 230 and the clip

arms **112** are extended out of the sheath **108** of the applicator **104** to move the clip arms **112** toward the tissue receiving configuration by, for example, sliding the spool **124** distally over the handle member **122**. Abutment of the distal surface **130** (in FIG. **6**) of the spool **124** with the positioning feature **128** provides tactile feedback to the user, indicating that the clip arms **112** are at the maximum open configuration, and that moving the spool **124** any further distally would result in the connector **116** extending distally out of the sheath **108**.

The clip arms **112** may be repeatedly moved between the tissue receiving and the tissue gripping configurations (the first and second configurations) until a target portion of tissue is received between the distal ends **140** of the clip arms **112**, as desired. Once the target portion of tissue is received between the clip arms **112**, the clip unit **102** is moved toward the tissue gripping configuration by moving the control member **110** proximally relative to the clip unit **102**. At this time, the restraining member **180** is also activated to prevent the target portion of tissue from being pinched between the locking mechanisms **150** and **152** as described in the first through fourth embodiments.

When it is confirmed that the desired portion of tissue is gripped between the clip arms **112** (e.g., portions of tissue on opposite sides of a bleeding wound), the control member **110** is drawn further proximally relative to the clip unit **102** (via the spool **124**) to lock the clip unit **102** in the closed configuration. That is, the clip arms **112** are drawn further proximally into the sheath **108** until the locking mechanisms **150**, **152** engage one another, locking the clip arms **112** relative to one another. The control member **110** is drawn proximally with respect to the locking sheath **108** until the connector **116** comes into contact with and abuts the shoulder **176** of the lumen **138** of the sheath **108**. The shoulder **176** prevents the connector **116** from moving proximally there past while a continued proximal force is exerted on the control member **110**.

When the distal end **118** of the control member **110** exerts a force on the connector **116** beyond a predetermined threshold value, the connector **116** deforms (e.g., the proximal opening **164** expands) to permit the distal end **118** to be released from the longitudinal slot **160**. Once the distal end **118** is released from the connector **116**, the applicator **104** may be withdrawn from the living body, leaving the clip unit **102** including the restraining member **180** in the body over the target tissue. If so desired, a new clip unit **102** including the restraining member **180** is then loaded onto the applicator **104**, in the same manner as described above, so that the device may then be used to clip a second portion of tissue. This process may be repeated using the same applicator **104** as many times as needed or desired.

The invention is not limited the above-described embodiments including connecting configurations between the clip unit **102** and the applicator **104**. FIG. **23** is a perspective view schematically illustrating another connecting configuration in which an applicator of an endoscope to be used in combination with a clip unit according to one exemplary embodiment, and FIG. **24** is a perspective view schematically illustrating the clip unit to be used in combination with the applicator of FIG. **23**.

As shown in FIG. **23**, an applicator **10** is a unit for inserting into an abdominal cavity (a control unit), and may include an insertion tube **20**, a control wire **30**, and a control unit **40**. The applicator **10** is used in combination with a clip unit **60**, for example, by inserting into a surgical tool insertion channel (not shown) of an endoscope. Therefore, the insertion tube **20** includes a distal end tip **21**, a distal end coil **22**, and a proximal end coil **24**. The control wire **30** includes a hook unit **31** at the distal end of the applicator **10** and wire **32**. The control unit **40** includes a control unit main body **41**, a slider **42**, a supporter **47**, and a thumb ring **18**. The main body **41** includes a slit **41***a* and a grip **41***b* The slider **42** includes a first slide member **51** and a second slide member **52** with a slit **52***b*,

As shown in FIG. **24**, a clip unit **60** can be fit to the hook unit **31**. The clip unit **60** may include a clip **61**, a connection member **62**, and a constraining pipe **63** as a tightening member. The clip **61** may have a loop (base) **61***a* made by bending a metallic plate material such as a flat spring made of stainless steel, for example, at substantially a central part. The clip **61** is crossed in vicinity of the loop **61***a*, and extended as a pair of clip arms **61***b* having an expanding characteristic in the state that the distal ends are separated. A tissue grasping part (a clip claw) **61***c* is formed at the end of the clip **61**.

The crossing part of the arms **61***b* of the clip **61** is made narrower than the distal end side, and the tissue grasping parts **61***c* are opposed to each other. The clip **61** can slide on the inner surface of the constraining pipe **63** when moving the clip **61** in the direction of pulling into the pipe **63**, but the clip **61** is engaged in the inner surface of the pipe **63** when moving the clip **61** in the direction reverse to the pulling-in direction.

The connection member **62** is formed by injection molding out of strong resin such, as liquid crystal polymer and polyamide synthetic fiber, for example. The connection member **62** is a cylindrical bar, and is engaged with the clip **61** inside the constraining pipe **63**.

The connection member **62** includes a stopper projection **62***i* connected to the constraining pip **63**, and the proximal end of the connection member **62** is forked into two branches that include a cutout **62***d* and an elastic arm **62***e*. The two branches are configured to receive the end of the arrowhead hook unit **31**.

The constraining pipe **63** is formed by injection molding of rigid resin having appropriate elasticity, such as a material more flexible than the clip **61**, for example, polyphthalamide (PPA) and polyamide (PA). By fitting the pipe **63** to the arms **61***b* of the clip **61**, the arms **61***b* of the clip **61** are closed. The constraining pipe includes a pair of wings **63***d* elastically retractable in the radial direction is formed.

While preferred embodiments of the invention have been described and illustrated above, it should be understood that these are exemplary of the invention and are not to be considered as limiting. Additions, omissions, substitutions, and other modifications can be made without departing from the spirit and scope of the present invention. Accordingly, the invention is not to be considered as being limited by the foregoing description, and is only limited by the scope of the appended claims

While various embodiments of the disclosed technology have been described above, it should be understood that they have been presented by way of example only, and not of limitation. Likewise, the various diagrams may depict an example schematic or other configuration for the disclosed technology, which is done to aid in understanding the features and functionality that can be included in the disclosed technology. The disclosed technology is not restricted to the illustrated example schematic or configurations, but the desired features can be implemented using a variety of alternative illustrations and configurations. Indeed, it will be apparent to one of skill in the art how alternative functional, logical or physical locations and configurations can be implemented to implement the desired features of the technology disclosed herein.

Although the disclosed technology is described above in terms of various exemplary embodiments and implementations, it should be understood that the various features, aspects and functionality described in one or more of the individual embodiments are not limited in their applicability to the particular embodiment with which they are described, but instead can be applied, alone or in various combinations, to one or more of the other embodiments of the disclosed technology, whether or not such embodiments are described and whether or not such features are presented as being a part of a described embodiment. Thus, the breadth and scope of the technology disclosed herein should not be limited by any of the above-described exemplary embodiments.

Terms and phrases used in this document, and variations thereof, unless otherwise expressly stated, should be construed as open ended as opposed to limiting. As examples of the foregoing: the term "including" should be read as meaning "including, without limitation" or the like; the term "example" is used to provide exemplary instances of the item in discussion, not an exhaustive or limiting list thereof, the terms "a" or "an" should be read as meaning "at least one," "one or more" or the like; and adjectives such as "conventional," "traditional," "normal," "standard," "known" and terms of similar meaning should not be construed as limiting the item described to a given time period or to an item available as of a given time, but instead should be read to encompass conventional, traditional, normal, or standard technologies that may be available or known now or at any time in the future. Likewise, where this document refers to technologies that would be apparent or known to one of ordinary skill in the art, such technologies encompass those apparent or known to the skilled artisan now or at any time in the future.

The presence of broadening words and phrases such as "one or more," "at least," "but not limited to" or other like phrases in some instances shall not be read to mean that the narrower case is intended or required in instances where such broadening phrases may be absent.

Additionally, the various embodiments set forth herein are described in terms of exemplary schematics, block diagrams, and other illustrations. As will become apparent to one of ordinary skill in the art after reading this document, the illustrated embodiments and their various alternatives can be implemented without confinement to the illustrated examples. For example, block diagrams and their accompanying description should not be construed as mandating a particular configuration.

What is claimed is:

1. A clip device, comprising:

a sheath;

a plurality of clip arms movable between a first configuration in which the plurality of clip arms are opened to receive a target tissue, and a second configuration, in which the plurality of clip arms are closed to grip the target tissue;

locking mechanisms respectively provided on the plurality of clip arms to engage one another for maintaining the second configuration; and

a restraining mechanism configured to be associated with the locking mechanisms to prevent the target tissue from being pinched between the locking mechanisms,

wherein the restraining mechanism includes a first restraining member and a second restraining member, distal end portions of which are respectively positioned more distally than the locking mechanisms, and

wherein, in the second configuration, the first restraining member and the second restraining member contact each other and extend distally to push the target tissue away from the locking mechanisms.

2. The clip device according to claim **1**, wherein the plurality of clip arms includes a first arm and a second arm; and the locking mechanisms are respectively disposed on inner surfaces of the first and second clip arms.

3. The clip device according to claim **2**, wherein the first restraining member and the second restraining member cross each other in the second configuration and are each configured as a stopping bar to prevent the target tissue from being pinched between the locking mechanisms.

4. The clip device according to claim **2**, wherein the first restraining member and the second restraining member are each configured as a curved bar having a protection front end surface.

5. The clip device according to claim **2**, wherein the locking mechanisms include a first locking member and a second locking member, and

wherein, in the first configuration, a first distance between the first restraining member and the second restraining member is less than a second distance between first locking member and the second locking member.

6. The clip device according to claim **2**, wherein, in the first configuration, the first restraining member and the second restraining member are apart from each other at a first distance,

wherein, in the second configuration, the first restraining member and the second restraining member are spaced apart from each other at a second distance, and

wherein the second distance is smaller than the first distance.

7. The clip device according to claim **2**, wherein the first arm and the second arm are configured to pivot about an axis and to rotate about the axis of the sheath.

8. The clip device according to claim **1**, wherein the restraining mechanism is provided distally relative to the locking mechanisms.

9. The clip device according to claim **1**, wherein the plurality of clip arms form a clip and wherein the locking mechanisms is configured to lock the clip in the second configuration.

10. The clip device according to claim **1**, wherein, in the first configuration, a distal end of the restraining mechanism is provided distally relative to a distal end of the locking mechanisms.

11. The clip device according to claim **1**, wherein the plurality of clip arms form a clip and wherein the clip device further comprises an operation wire inserted into the sheath and configured to translate the clip between the first configuration and the second configuration.

12. The clip device according to claim **11**, wherein the operation wire is configured to be detachably attached to the plurality of clip arms.

13. The clip device according to claim **11**, wherein the operation wire is configured to move along a longitudinal axis of the sheath and to protrude from a distal end of the sheath.

14. The clip device according to claim **1**, wherein the restraining mechanism extends inwardly from an inner surface of the plurality of clip arms.

15. The clip device according to claim **1**, wherein, in the first configuration, the locking mechanisms are located outside the sheath, and

wherein, in the second configuration, the locking mechanisms are located inside the sheath.

16. The clip device according to claim 1, wherein the restraining mechanism are located with the locking mechanisms.

17. A clip device, comprising:

a sheath including a lumen and at least one open end;

a plurality of clip arms movable between a first configuration in which the plurality of clip arms are opened to receive a target tissue, and a second configuration, in which the plurality of clip arms are closed to grip the target tissue;

locking mechanisms respectively provided on the plurality of clip arms to engage one another for maintaining the second configuration; and

a restraining mechanism configured to be associated with the locking mechanisms to prevent the target tissue from being pinched between the locking mechanisms,

wherein the plurality of clip arms includes a first arm and a second arm; and the locking mechanisms are respectively disposed on inner surfaces of the first and second clip arms,

wherein the restraining mechanism includes a first restraining member and a second restraining member, distal end portions of which are respectively positioned more distally than the locking mechanisms, and

wherein the first restraining member and the second restraining member contact each other and are deformed to extend distally in the second configuration, thereby pushing the target tissue away from the locking mechanisms.

18. A clip device, comprising:

a sheath;

a plurality of clip arms movable between a first configuration in which the plurality of clip arms are opened to receive a target tissue, and a second configuration, in which the plurality of clip arms are closed to grip the target tissue;

locking mechanisms respectively provided on the plurality of clip arms to engage one another for maintaining the second configuration; and

a restraining mechanism configured to be associated with the locking mechanisms to prevent the target tissue from being pinched between the locking mechanisms,

wherein the restraining mechanism includes a first restraining member and a second restraining member, distal end portions of which are respectively positioned more distally than the locking mechanisms, and

wherein, in the second configuration, the first restraining member and the second restraining member contact each other and are each deformed distally to push the target tissue away from the locking mechanisms.

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